SynGen™

WashPRO ™ Alpha System

USER MANUAL

Sacramento, CA, USA
support@syngeninc.com | Customer Service: 1.844.363.0709 or 1.916.256.2423
Fax: 1.916.706.0832

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SynGen Inc.
Sacramento, CA. USA
Phone: (916) 706-0923

It is strongly recommended that all users read this manual in its entirety before using the WashPRO™ System.

ADVISORY NOTE:

This user manual is part of an Alpha product release and is considered a work in progress. The intention of this user manual is to provide a basic set of generalized user instructions. Specific instructions for specific cell types are not included.

This Alpha system is Production Equivalent as of June 2015.

Any comments, suggestions for change, feature requests, etc. may be sent by email to sales@syngeninc.com.

VARIATIONS IN APPEARANCE OR FUNCTION BETWEEN PRODUCT ON SITE AND THE MANUAL MAY OCCUR. SEND FEEDBACK AND COMMENTS TO SUPPORT@SYNGENINC.COM.

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Section 1: Introduction

The WashPRO™ Alpha System is used for the washing and concentration of cells from cell cultures, frozen cells, or other concentrated cell populations. This is an Alpha system and not a commercially-released product.

This Alpha is Production Equivalent as of June 2015.

Indications for Use

The WashPRO System is intended for laboratory use to allow for fast, automated, and reproducible washing of cultured cells in a closed and sterile environment. The Alpha system is intended for testing and validation for the purpose of product development and improvement prior to design finalization.

Principles of Operation

The SynGenX™-WASH Disposable Set is composed of two Disposable Cartridges interconnected by an input tubing set, which allow for precise distribution of cell harvest and diluents into the Cartridges. Tube connections from each Cartridge's harvest compartment to the main compartment of the opposite Cartridge allow for quick, easy, and sterile preparation of the cells for subsequent wash cycles.

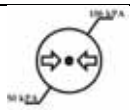
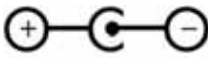
The WashPRO System is composed of the following:

- SynGenX™-WASH Disposable Set
- Elevated strain gauge capable of holding bags for cultured cell solution or diluent
- Two rotating platforms for the Disposable Set to facilitate transfer
- Pump to apply positive or negative pressure to the Disposable Set, facilitating and controlling the flow rate of fluid between Cartridges and bags
- Pinch valves to control movement of fluid and/or cell suspension between Cartridges and bags
- User interface for the operator, which supports downloading processing data to a PC

Symbol Key

The following symbols are used on the WashPRO System labeling, packaging, or within the User Manual.

SYMBOL	MEANING
	Special disposal for electronic waste required
REF	Product or Part Number
	Manufactured By

SYMBOL	MEANING
	Serial Number
	Warning to be observed by the user
	Caution to be observed by the user
	Keep dry
	A note to be observed by the user
	Storage Temperature Range
	Storage Humidity Range
	Storage Pressure Range
	Consult Instructions For Use
	Direct Current
	Negative Tip Polarity

Abbreviations

Below are abbreviations that are used in the User Manual and their associated definitions.

ABBREVIATION	DEFINITION
BC	Buffy Coat – Concentration of platelets and white blood cells in a solution that contains some RBCs and plasma
CSV	Comma Separated Values
HES	Hydroxyethyl Starch
IEC	International Electrotechnical Commission
LED	Light Emitting Diode
ME	Manufacturer's Equipment

Abbreviation	Definition
MNC	Mononuclear Cells
PC	Personal Computer
PDF	Portable Document Format
RBC	Red Blood Cells
RCF	Relative Centrifugal Force or “G” Force
RF	Radio Frequency
RPM	Revolutions Per Minute
WBC	White Blood Cells
x g	Gravitational Acceleration Force

Section 2: Safety

Warnings

A **Warning** is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

READ THIS USER MANUAL COMPLETELY PRIOR TO USING THE WASHPRO™ WORKSTATION

- Always follow established procedures for handling and discarding biohazardous materials.
- The SynGenX™-WASH Disposable Set is a single-use device with a sterile, non-pyrogenic fluid path. Do not use if packaging or product is damaged. Do not re-sterilize.
- No modification of this equipment is allowed. Only SynGen™ Inc. authorized replacement parts may be used.

Cautions

A **Caution** is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. The caution statement includes the caution that should be taken to avoid the hazard.

- Follow aseptic procedures.
- Operators should be trained on the WashPRO prior to initial use.
- Avoid liquid contact with the WashPRO™ Control Module internal components. In the event that liquids enter the Control Module, stop using and turn off the Control Module. Return the Control Module to SynGen Inc. for service.
- Do not to insert any objects, including fingers, into the Control Module while powering on.
- Handle the SynGen™ Docking Station with care.
- When connected to another device, the overall system must be evaluated to the IEC 60601-1 3rd edition by the end user.
- Avoid dropping any of the components of the WashPRO system as this may cause damage.
- Keep the SynGenX-WASH Disposable Set upright during and after filling. Do not invert once filled.
- The WashPRO Control Module battery should be charged in the SynGen Docking Station overnight or for at least 6 hours prior to initial use.
- Do not exceed 2000 x g centrifugation at any time as an inappropriate transfer of blood between compartments may occur, causing a loss of cell functionality requiring the buffy coat to be discarded.
- Only use the SynGen™ DataTrak software for downloading and storage of processing information.

- Ensure that the computer is virus-free and has the latest update of antivirus software prior to installing the DataTrak Software.
- Update the operating system, service pack, and antivirus software on a regular basis.
- Do not leave the internet active while installing or using the DataTrak Software.

Safety and EMC Compliance Information

The WashPRO™ Workstation is an Alpha system and has not been submitted for safety and compliance testing for this phase of the development.

Disclaimer

The WashPRO System, including all hardware, software, and consumables are considered Research Only Devices or Investigation Only Devices.

The products are in the process of development, and have not completed all of the design verification testing, including safety testing. Device performance and usability feedback from end users will be considered but may or may not be used in the final product design. All device performance and usability feedback remains the property of SynGen Inc.

There may be small differences in appearance in products in actual use versus those images found in this User Manual.

Section 3: WashPRO™ System Description

The WashPRO™ System will be used for manufacturing cellular products in a cGMP laboratory or manufacturing facility, including the concentration and washing of ex vivo expanded cultured cells.

The WashPRO System consists of the following components:

Component	Part Number
WashPRO™ Workstation	TBD - Alpha
WashPRO™ Control Module with its associated firmware	SGI-0046
SynGenX™ Docking Station with its associated firmware	SGI-0120
SynGen™ DataTrak Software	2.0
SynGenX™-WASH Disposable Set	TBD - Alpha
WashPRO™ Software	TBD - Alpha

An accessory kit is provided with the WashPRO System including a 1 kg calibration weight, cables, and a bucket for draining waste.

The WashPRO System **requires** the following instrumentation for operation. These are not provided by SynGen Inc.

- Tubing Sealer for PVC and EVA tubing
- Sterile Connection Device
- Thermo Scientific Sorvall™ Legend™ XT or XTR Centrifuge with 750 mL buckets (or equivalent)
- Computer (e.g., desktop or laptop PC or tablet) with Windows® 7 or 8.1 Operating System and at least one available USB port (additional USB port required for optional barcode scanner)
    - For Windows 7 Operating Systems, **only** USB 2.0 Ports are compatible with the DataTrak software

Materials and equipment that are required but not supplied:

- Cell culture sample (concentrated to a total volume of less than 480 mL) loaded into a transfer bag
- Cell wash medium loaded into a transfer bag
- Cell medium for final suspension
- Biological Safety Cabinet or clean room area
- Digital Scale
- Label Printer(s) for component labeling
- Syringes for sample (if applicable)
- Labels for components and sample tubes
- Final harvest collection bag or container

SynGenX™-WASH Disposable Set

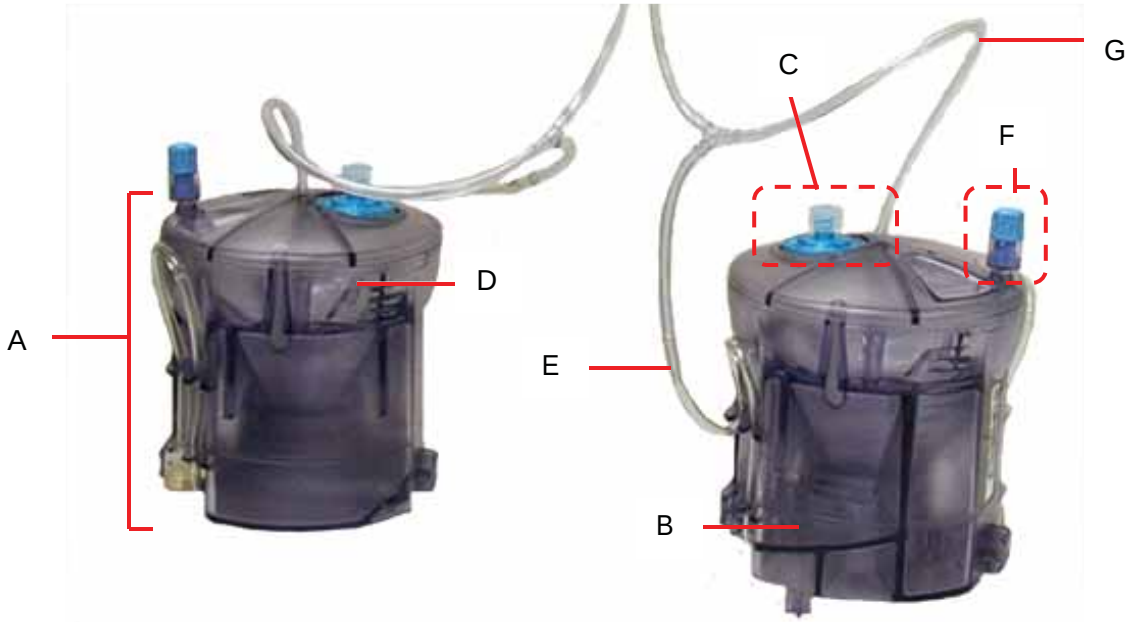
The SynGenX™-WASH Disposable Set is composed of two Disposable Cartridges interconnected with additional input tubing, which allows for even distribution of cell harvest and diluents into both Cartridges. Tube connections from each Cartridge's harvest compartment to the main compartment of the opposite Cartridge allow for quick, easy, and sterile preparation of the cells for subsequent centrifugation for washing.

Each Cartridge in the Set can accommodate up to 240 mL of cell culture and / or wash medium in the central funnel compartment. The harvest compartment can accommodate up to 30 mL of harvested cells and suspension media.

The cell culture-filled Disposable Set is then placed into the WashPRO™ Control Modules for subsequent centrifugation following a preprogrammed profile.

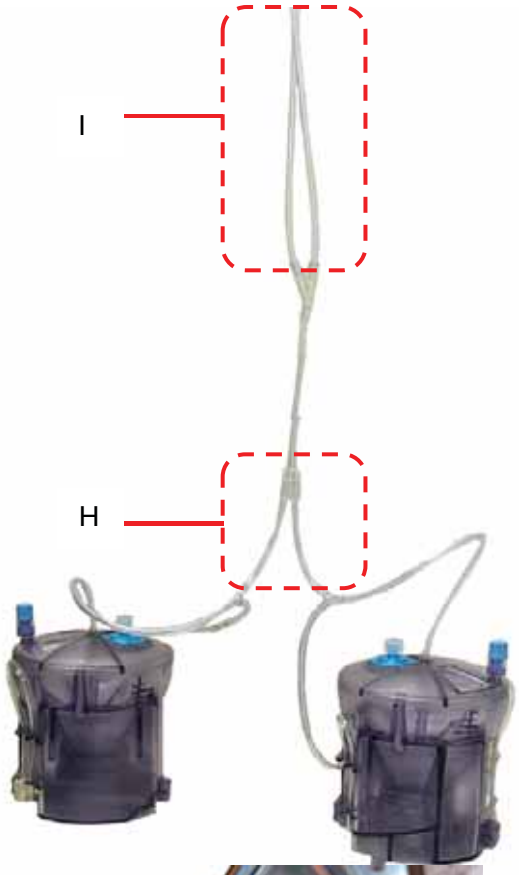
Integrated within the Disposable Cartridge are mechanisms that pinch or release the tubing, allowing for transfer of the cellular components during centrifugation. This operation is managed by the WashPRO Control Modules.

Disposable Set Components



A. The **Disposable Cartridge Housing** contains the individual compartments (Harvest Compartment, and Central Funnel Compartment) and integrated pinch mechanisms.

B. The **Harvest Compartment** is where the harvested final product is collected in a small volume of suspension media.



C. The **Air Filter** is 0.2 micron hydrophobic filter that facilitates air management during filling the Disposable Cartridges or pushing fluid out of the Cartridges. The **Vacuum/Pressure Tube** is connected to this port – with the task of providing a vacuum / air pressure system to facilitate fluid transfer out of the Disposable Cartridge and between the Cartridges.

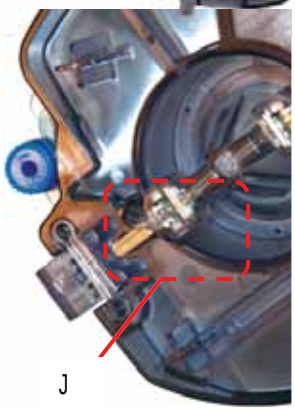
D. The **Central Funnel Compartment** is where cell cultures and media are loaded into the Disposable Cartridge.

E. The **Harvest Compartment Access Tube(s)** are for the filling of the harvest compartment with suspension medium, transfer of the harvested cells to the central funnel of the opposite Cartridge, and the draining of the final harvest into a collection bag.

F. The **Waste Line Connector Port** is where spent media is sent to a waste container.

G. The **Central Funnel Tube(s)** enable the flow of cell culture and media into the central funnel compartment.

H. The **Bridge Tubing** is the length of tubing joining the upper Media and Culture bag tubing to the lower Disposable Cartridge Harvest Compartment Access Tubes and Central Funnel Tubes.



I. The **Media Bag** and **Cell Culture Bag Tubing** provide connections through sterile docking or sterile connection to the Disposable Set.

J. The **Pinch Clamps** are controlled by the Control Modules to pinch and release the tubing to control the movement of cells and media between compartments.

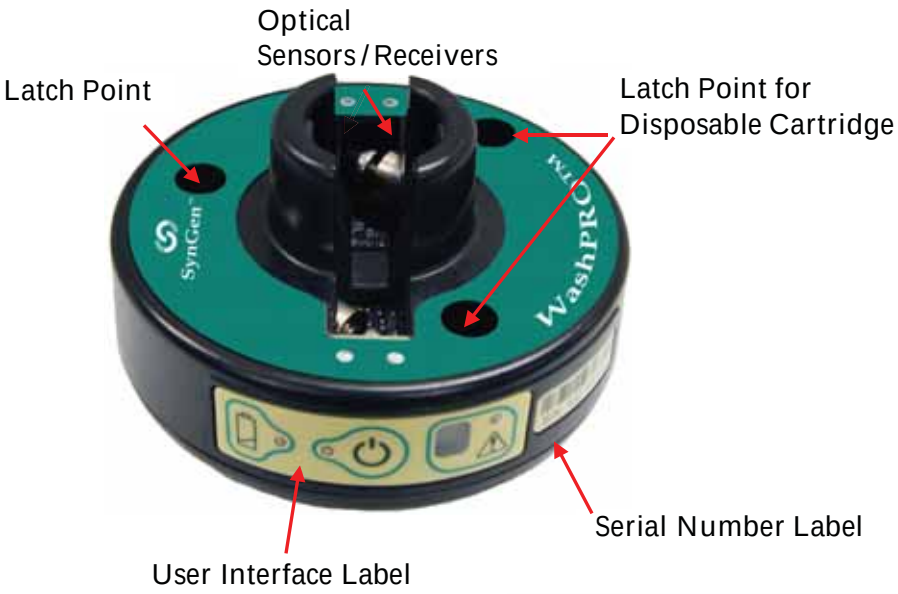
WashPRO™ Control Module

The WashPRO™ Control Module is a lithium ion battery-operated, microprocessor-controlled, electromechanical device. Two motor / gear / cam assemblies in the Control Module rotate in order to operate an integrated tube pinch / release mechanism that enables transfer of cultured cells to the harvest compartment. The Control Module is also equipped with an accelerometer to measure acceleration and four optical sensors that detect interfaces between cell populations and cell culture media.

The Control Module firmware is the computer code that provides the operating instructions to the electromechanical components of the Control Module. It gathers and stores information during each harvesting run including accelerometer readings, infrared optical sensor readings,

and timing and duration of the pinch and release of the cell fraction transfer tubes. The collected data serves to support cGMP compliance by documenting each harvesting run.

Control Module Components



The Control Module components and display elements are described below:

Optical Sensors and Receivers: Four optical sensors and receivers that detect the cell interfaces during centrifugation.

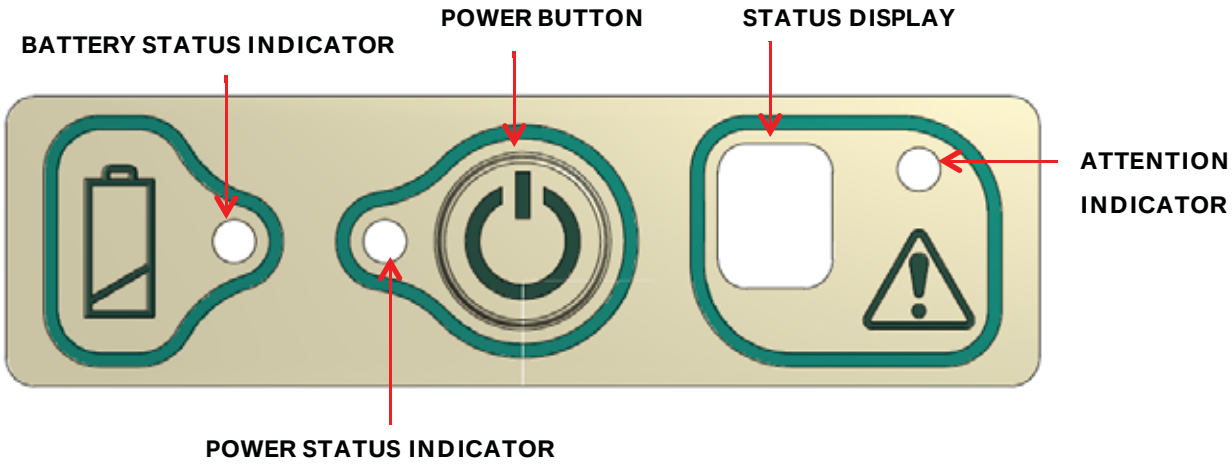
Latch Point for Disposable Cartridges: The three connections for latching the Disposable Cartridge to the Control Module.

Device Information Label: Provides information specific to the Control Module as well as SynGen Inc. contact information.

Electrical Connectors for Pogo Pins: The connectors that make contact with the Docking Station Pogo Pins and facilitate data transmission and charging.

Serial Number Label: Control Module barcode and human readable text label.

User Interface Label



BATTERY STATUS INDICATOR: Steady green if the battery has a sufficient charge to perform a harvest process. Steady red if the battery is insufficiently charged. The operator should immediately charge the battery.

When the Control Module is placed on the Docking Station for charging, the battery status indicator will blink at the following rates in response to battery charge falling below the following thresholds:

- Battery Voltage < 3.95V: 1-blink pattern
- Battery Voltage ≥ 3.95V and < 4.1V: 2-blink pattern
- Battery Voltage ≥4.1V and < 4.15V: 3-blink pattern
- Battery Voltage ≥ 4.15V: Steady (fully charged)

POWER BUTTON: Press this button for approximately one (1) second to power on the Control Module. Press it for approximately three (3) seconds to power off the Control Module.

POWER STATUS INDICATOR: Green if Control Module is powered on. Not illuminated if Control Module is powered off.

STATUS DISPLAY: Displays the status or error code of the Control Module. Standard Status Codes are described below. Refer to the **Troubleshooting** section for error codes and additional information.

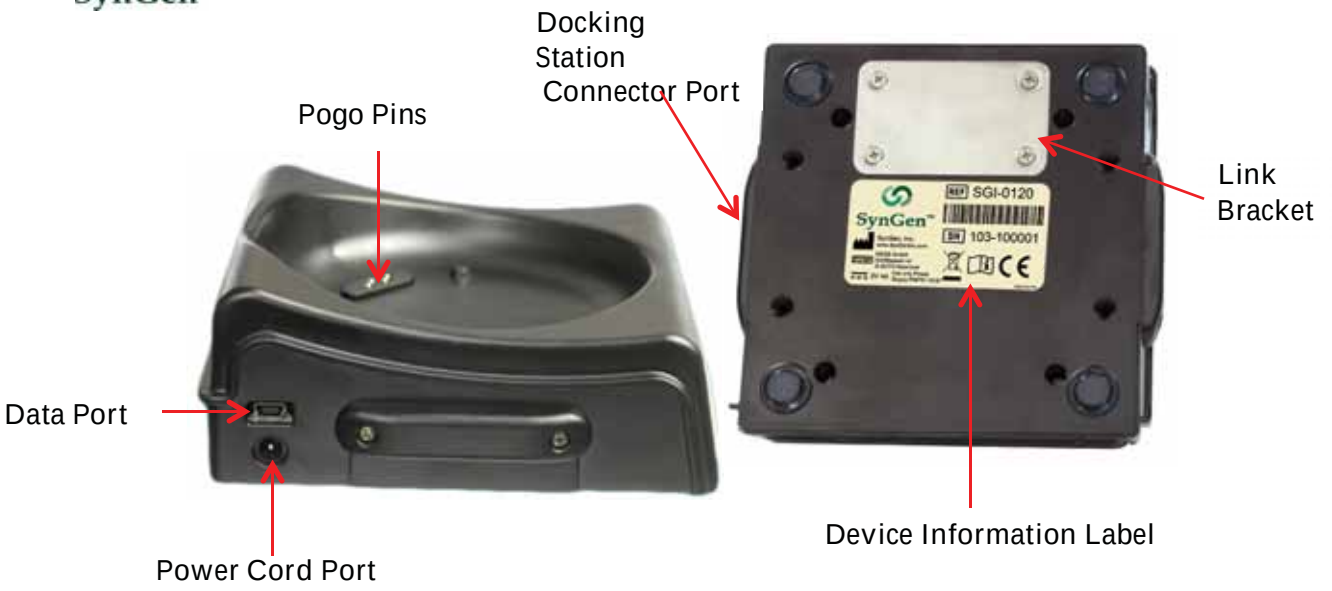
CHARACTER	DEFINITION	PROCESS DESCRIPTION
0	Ready to Operate	The Control Module is ready for processing
P	Pass	The process is has completed successfully
dP	Data Present	The data needs to be downloaded in preparation for a new process

ATTENTION INDICATOR: Green if the Control Module is ready for processing or has successfully completed a centrifugation process. Red if the Control Module has failed a centrifugation process, has gone into an error state, or the Control Module was powered down prior to downloading the data. The operator should assess which of these situations has occurred, and take appropriate actions to remedy.

SynGen™ Docking Station

The SynGen™ Docking Station is a multifunctional system component that concurrently charges the battery of the Control Module and enables transmission of data to and from the Control Module and a host PC. Each Docking Station holds one Control Module at a time. Four Docking Stations can be connected in series and powered by a single cable to allow charging of up to four Control Modules simultaneously. A single Docking Station can be used independently for both data transfer and Control Module charging.

The components of the Docking Station are described below:



Pogo Pins: Retractable pins which align and contact with electrical connectors on the bottom of the docked Control Module for data communication and battery charging. These pins are inactive when no Control Module is docked.

User Interface Label: Identifies the device and allows the user to see an LED with three states.

- Green if a Control Module is present and charging.
- Red if no Control Module is present or is present but not seated properly, or Control Module is not functional. The operator should assess which of these situations has occurred and take appropriate actions to remedy.
- Not illuminated if the Docking Station is not receiving power.

Docking Station Connector Port: Allows for side-by-side linking with up to four Docking Stations. The connectors are located on each side of the Docking Station.

Data Port: Port for connection to the host computer via the USB cable.

Power Cord Port: Port for connection to the external power source via the power cable. To remove mains power, unplug the cable from the wall.

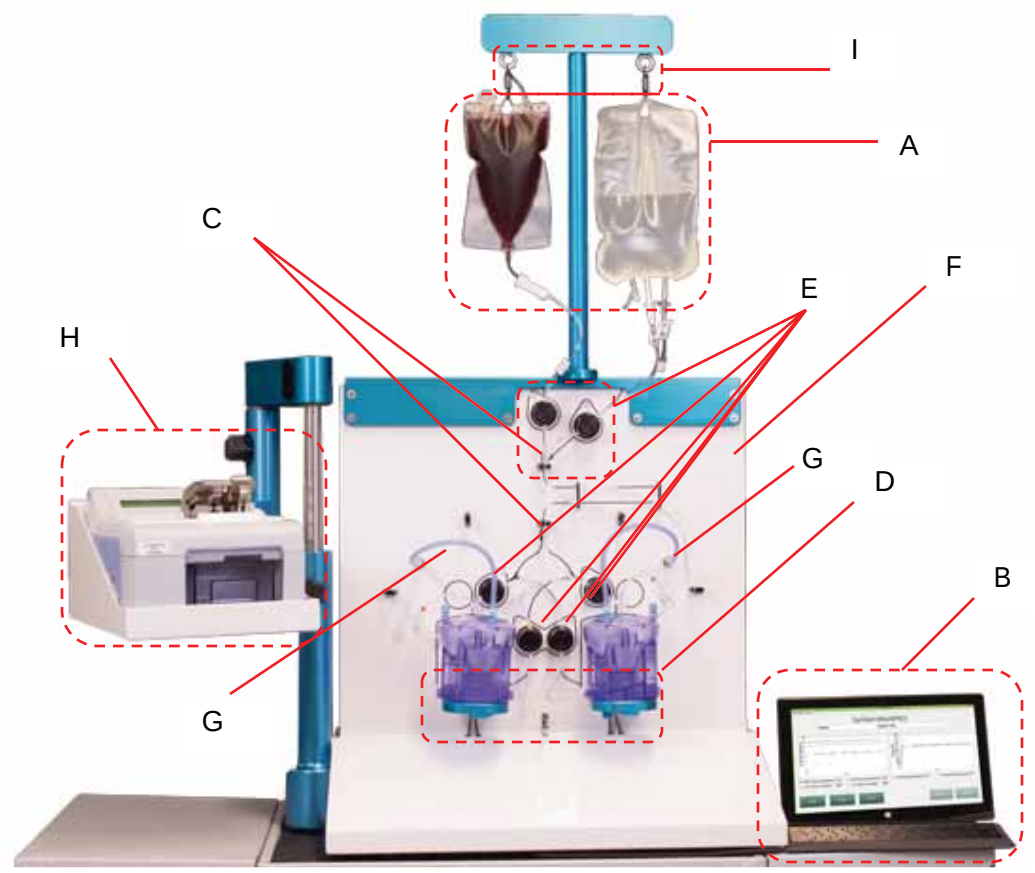
Device Information Label: Provides information specific to the Docking Station as well as SynGen Inc. contact information.

Link bracket: Provided on every Docking Station to lock together the side-by-side linked Docking Stations.

WashPRO™ Workstation

The WashPRO Workstation is the basic automated processing system that enables fluid transfer between cell cultures and culture media bags into the Disposable Set.

The WashPRO Workstation components include:



A. **Elevated strain gauge/load cell** for holding a cultured cell solution bag (left) and a diluent wash bag (right).

B. A **computer** to control the WashPRO Workstation.

C. Upper and Lower **Y connector holders** for the SynGenX™-WASH Disposable Set.

D. Two **rotating holders** for the Disposable Set to facilitate transfer of waste to the waste bag and mixing of cells collected in the harvest compartments.

E. Six **pinch valves** for closing tubes on the Disposable Set during processing.

F. A **pump** to apply positive or negative pressure to the Disposable Set to facilitate and control the flow rate of fluid between the various bags and Disposable Set compartments during processing.

G. Two **vacuum/pressure tubes** to interface between the pump and Disposable Cartridge.

H. **Sterile Docking Device** mounted on a swing arm for easy use.

I. **Load Cell Hooks** provide volume measurement during operation.

A user interface is provided for the operator and a computer interface is provided for downloading data to a PC.

WashPRO™ Control Software

The WashPRO™ Control software provides the basic controls for the Workstation. There is no data tracking capability in the Alpha product release. The Control Module will track centrifugation data for download into the SynGen™ DataTrak software.

SynGen™ DataTrak Software

Introduction

The SynGen DataTrak software provides the interface between the operator and the WashPRO Control Module, Disposable Cartridge, and Docking Station through a host computer. It downloads processing and system information and stores it in a database on the host computer. The data collected includes information gathered during each processing run and serves as a means to support cGMP compliance. The SynGen DataTrak System software includes the Microsoft® MS SQL Server 2008 R2 Express Edition as the database server for a host computer.

***NOTE**: The SynGen DataTrak Software is broadly used for several products within the SynGen family. The DataTrak Software compatibility for the WashPRO System is limited to data transfer from the Control Modules and tracking lot numbers of the Disposable Sets.*

***NOTE**: The CryoPRO Workstation and CryoPRO-2 bag set are not used with the WashPRO, however they will still be represented in DataTrak screen shots. Actual data created using the WashPRO Control Modules may differ from the data shown in this Manual.*

Intended Use

The DataTrak Software is intended for use with WashPRO Control Module, X-WASH Disposable Set, and SynGenX Docking Station. As of the release of the Alpha WashPRO Systems, no information on the specific processing of the WashPRO Workstation is captured within DataTrak.

Software users should be familiar with the applicable WashPRO System components prior to using the DataTrak Software. The DataTrak Software is not intended for use with computer system specifications other than those listed in the Computer System Requirements.

Computer System Requirements

A computer, printer, USB hub, and barcode scanner are not provided with the software. A SynGen representative will install and configure the software application for customer use.

The **minimum** required computer specifications are:

- Windows® 7 or 8.1 Operating System
- Microsoft® .Net Framework 4.0
- Minimum Intel® Core i5 1.7 GHz processor or equivalent
- Minimum 4 GB RAM of memory
- Minimum Hard disk size of 120 GB
- Minimum Hard disk free space of 100 GB* dedicated to the SynGen™ DataTrak database
- At least 2 available USB Ports:
    - For Windows 7 Operating Systems, **only** USB 2.0 Ports are compatible with the DataTrak software

The **recommended** required computer specifications are:

- Windows® 7 or 8.1 Operating System
- Microsoft® .Net Framework 4.0
- Minimum Intel® Core i5 1.7 GHz processor or equivalent
- Minimum 8 GB RAM of memory
- Minimum Hard disk size of 500 GB
- Minimum Hard disk free space of 200 GB* dedicated to the SynGen™ DataTrak database
- At least 2 available USB Ports:
    - For Windows 7 Operating Systems, **only** USB 2.0 Ports are compatible with the DataTrak software

* All data captured by DataTrak is stored within a database. The storage size requirements for this database are dependent on the number of samples run in a year.

Here are some rough guidelines on annual requirements of data storage:

Number of Processes (Samples) Run in an Year	Estimated Storage Capacity Required for 1 Year of Data	Estimated Storage Capacity Required for 5 Years of Data
2500	2 GB	10 GB
10000	8 GB	40 GB
25000	18 GB	90 GB
50000	35 GB	175 GB

User Profiles

The DataTrak software has three user profiles that are designed to restrict software operations based on level of responsibility.

Lab Technician User

The Lab Technician User can download the data from the WashPRO System components, view the data history, customize their software views and change their password.

Lab Supervisor User

The Lab Supervisor User level has all of the abilities of the Lab Technician User profile as well as the additional ability to approve reports.

Administrator User

The Administrator User profile is a management function level only. The Administrator User can add, edit, or inactivate users, serial numbers of the system equipment, and lot numbers of the disposable components. The Administrator User does not have the ability to download data from the WashPRO System components or view data history. This ability is restricted to the Lab Supervisor and Lab Technician User profile.

DataTrak Software Description

The DataTrak software is divided into two modes of functionality: Administration and Operations.

Administration Mode

The Administration mode includes two sections of operating functions: Administration and Preferences. The active section will be highlighted in yellow. The Administration section provides the data record of users, equipment, and materials. Once data is entered it cannot be deleted—only edited or made inactive. Click the **LOGOUT** button to exit the administrative area and return to the login screen.

Administration Section

The Administration section includes the following selections on the left side of the display screen for administrative functions. Selected sections will be highlighted in yellow.

User Profile

Includes the following fields for data entry: **USER ID, LAST NAME, FIRST NAME, PHONE NUMBER, USER ROLE** and **ACTIVE** checkbox. Entered User information is displayed in a table below the data entry fields.

Control Module

Primary screen displays a **REGISTER CONTROL MODULE** button and a table with the registered **CONTROL MODULE ID, RECEIPT DATE** and **ACTIVE** state. Clicking the **REGISTER CONTROL MODULE** button displays the **REGISTER CONTROL MODULE** field, which includes a field for the S/N barcode of the Control Module, **DATE RECEIVED** dropdown menu and a **REGISTER** button.

Centrifuge

Includes the following fields for data entry: **CENTRIFUGE SERIAL NUMBER, DESCRIPTION, CALIBRATION DUE DATE** dropdown menu, and **ACTIVE** checkbox. Entered centrifuge information is displayed in a table below the data entry fields.

Disposable Cartridge

Includes the following fields for data entry: **DISPOSABLE CARTRIDGE LOT NUMBER, QUANTITY, EXPIRATION DATE** dropdown menu, **LOT RECEIVED DATE** dropdown menu and **ACTIVE** checkbox. Entered Disposable Cartridge information is displayed in a table below the data entry fields.

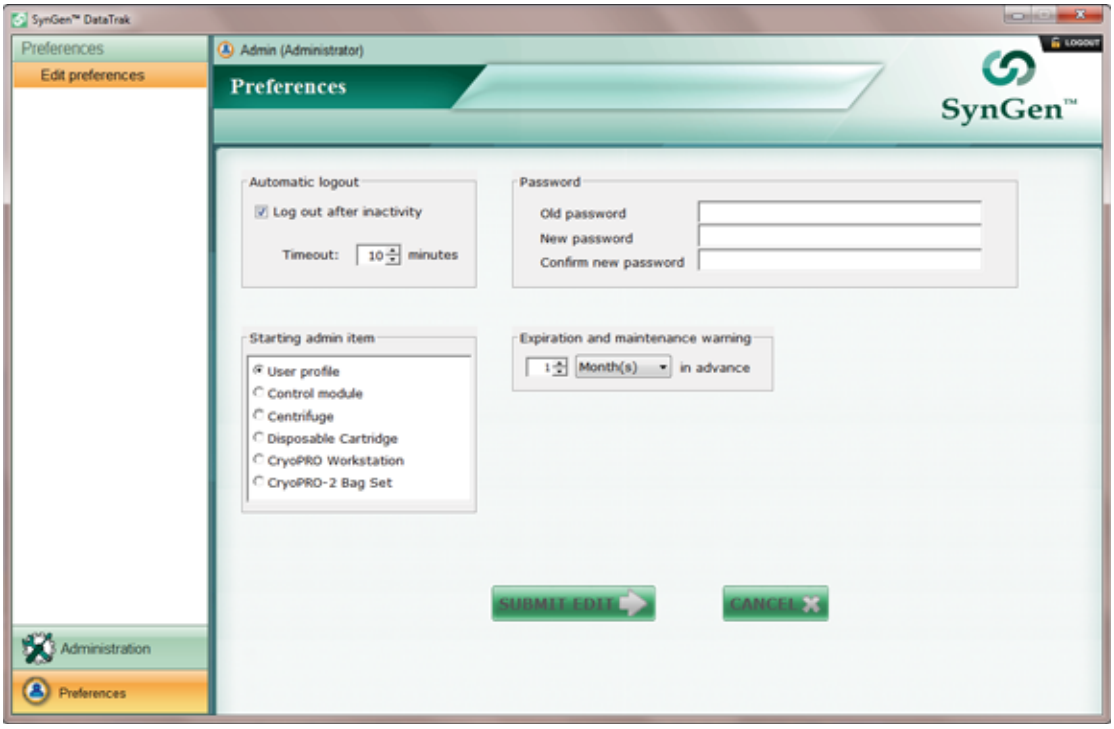
CryoPRO Workstation (this section not applicable)

CryoPRO-2 Bag Set (this section not applicable)

Preferences Section

The **PREFERENCES** section allows the Administrator User to configure the software as indicated below. Click the **SUBMIT EDIT** button to accept the entry or the **CANCEL** button to cancel the entry.

.



Automatic logout

Includes a **LOG OUT AFTER INACTIVITY** checkbox and an up / down selection menu to configure a timeout from 10 to 500 minutes in 10 minute increments.

Starting admin item

Includes selection buttons for the field displayed upon Admin login.

Password

Includes the following entry fields for changing a login password: **OLD PASSWORD, NEW PASSWORD,** and **CONFIRM NEW PASSWORD**.

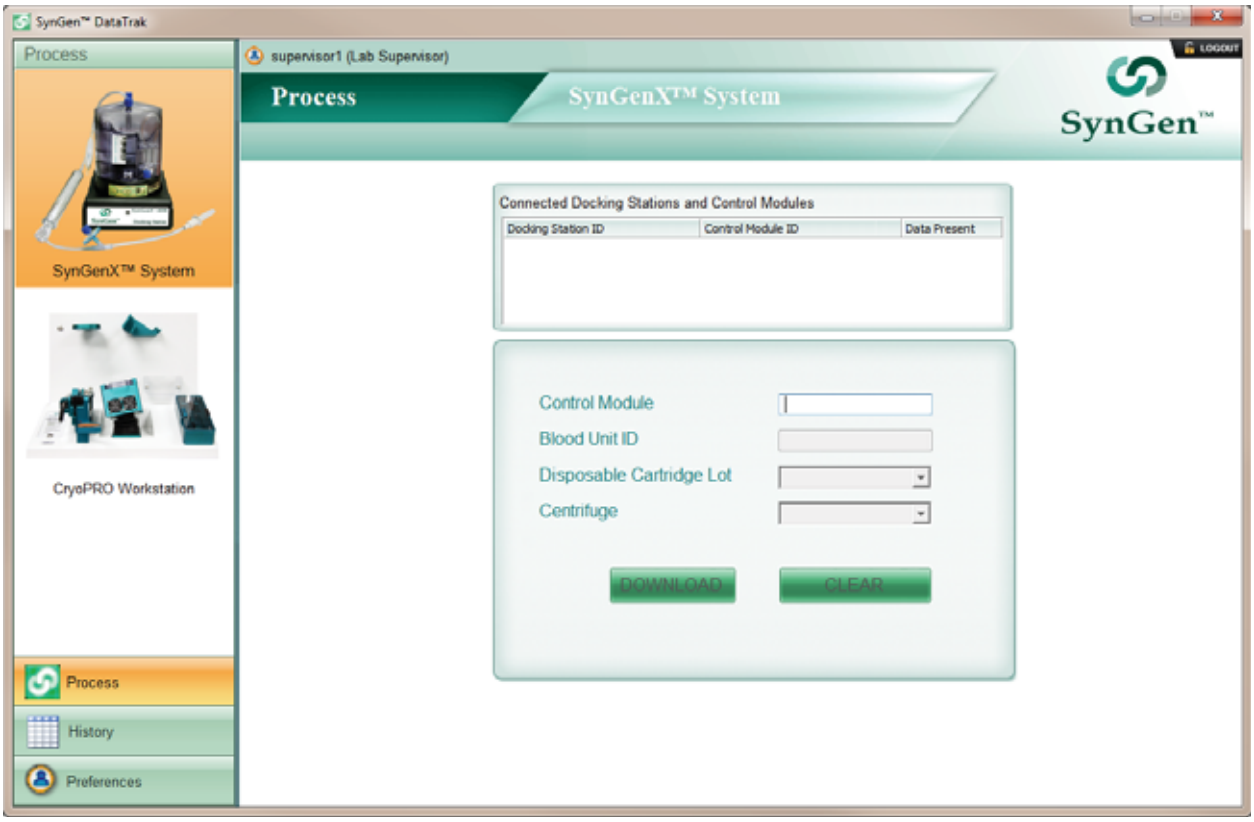
Expiration and calibration warning

Includes up and down keys and dropdown menu selection to designate the amount of advance notification of expiration and calibration due dates in days, weeks, or months.

Operations Mode

1. The **OPERATIONS** mode includes the three sections of operating functions: **PROCESS, HISTORY**, and **PREFERENCES**. The **PROCESS** section allows the user to download the data from the WashPRO System components. The data cannot be edited by a user. Click the **LOGOUT** button to exit the **OPERATIONS AREA** and return to the login Screen. The **PROCESS** section includes the following process options for data entry.

Process Section



SynGenX™ System

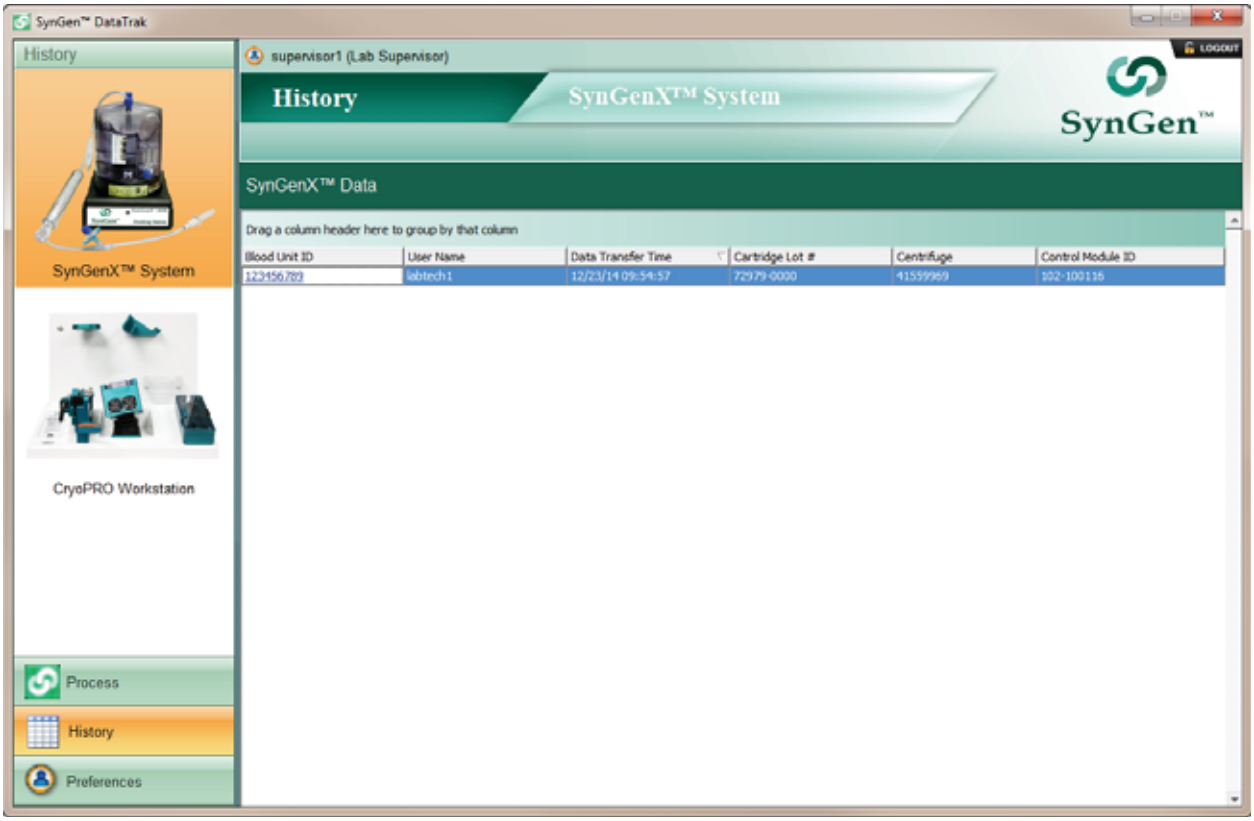
Select the SynGenX™ System picture to display the **CONTROL MODULE DOWNLOAD** field. Includes the following required entries for download: **CONTROL MODULE SERIAL NUMBER, BLOOD UNIT ID, DISPOSABLE CARTRIDGE** dropdown menu, and **CENTRIFUGE** dropdown menu. A green checkmark will indicate a valid entry and a red "X" will indicate and invalid entry for the Control Module Serial Number, the Centrifuge Serial Number, and the Disposable Cartridge Lot Number.

CryoPRO Workstation (this section not applicable)

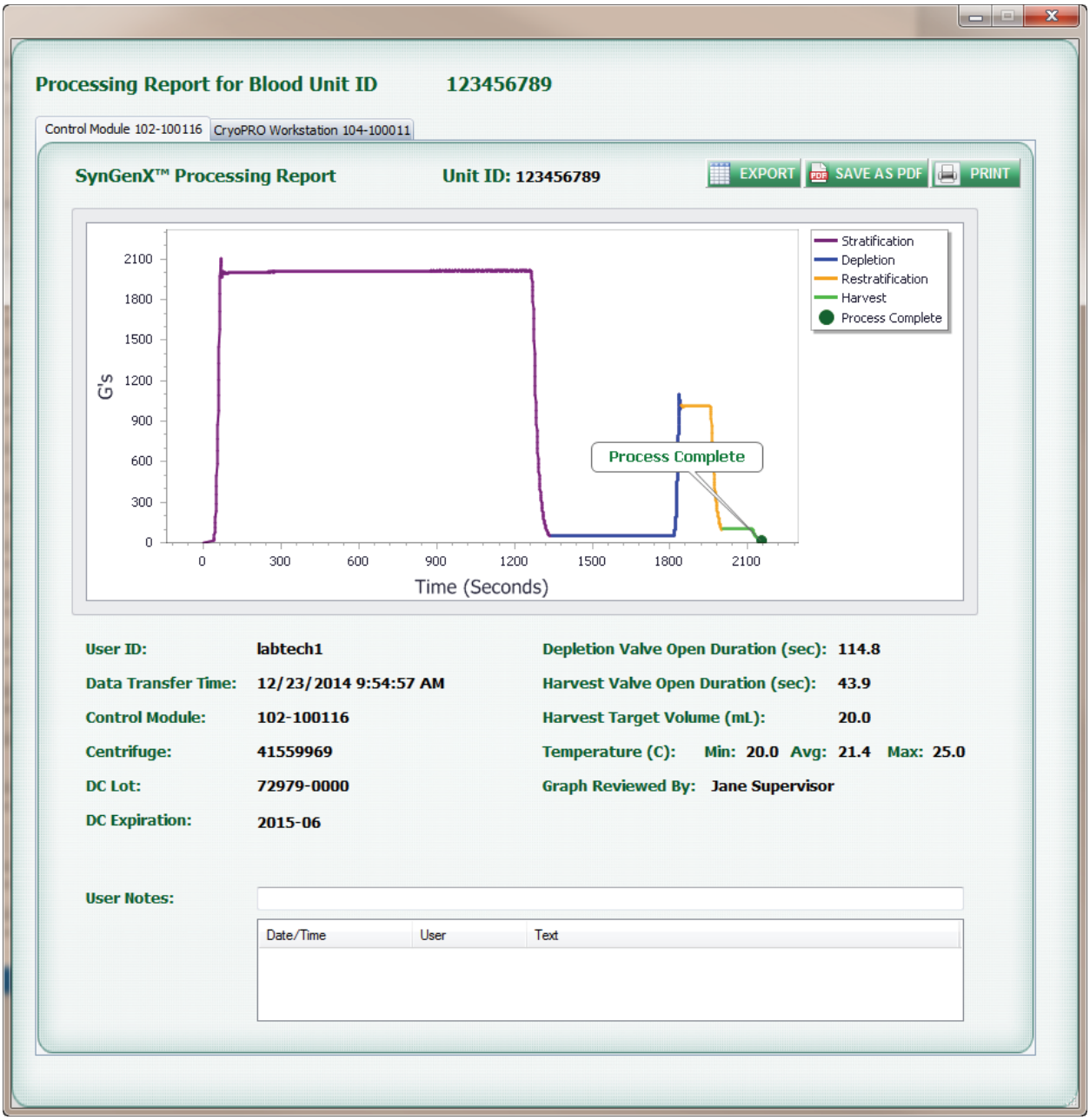
History Section

The **HISTORY** section will display the data records for selected component (e.g., if the **SYNGENX SYSTEM** section is selected, the download data from the Control Modules will be listed).

To review a **PROCESSING REPORT,** click the appropriate Blood Unit ID.



The **CONTROL MODULE PROCESSING REPORT** contains the following information:

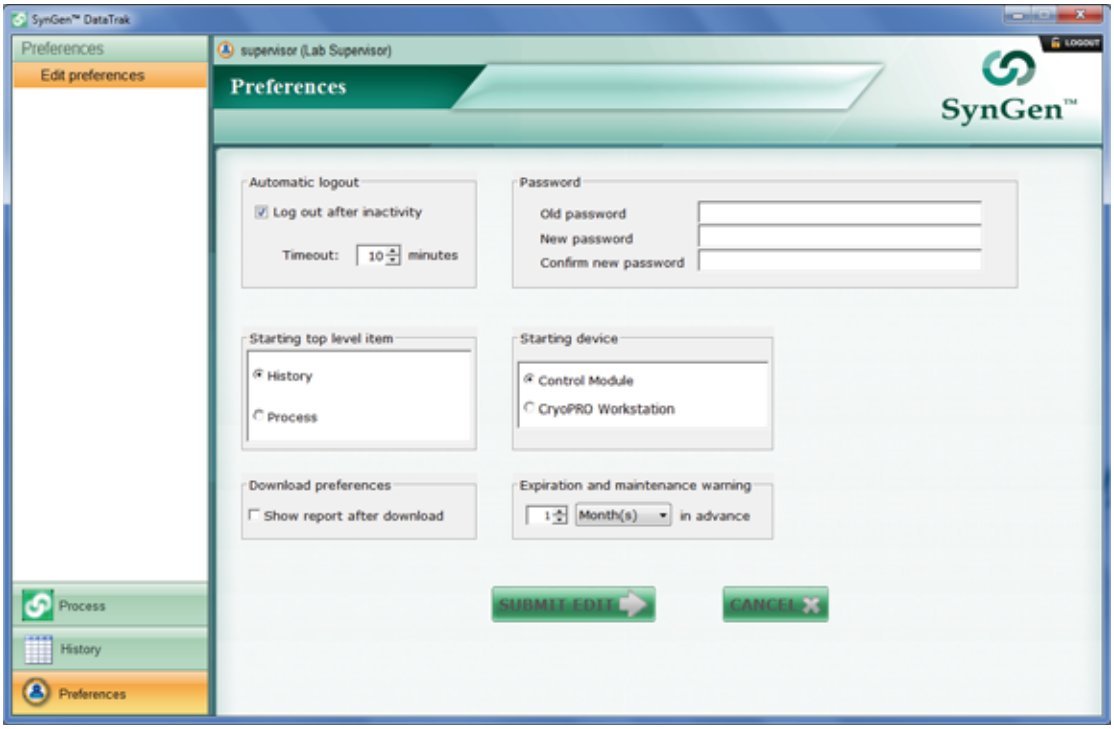


UNIT ID	The Blood Unit ID for the process report
EXPORT button	Allows the data to be exported as a CSV file
SAVE AS PDF button	Allows the report to be saved as a PDF file.
PRINT button	Allows the report to be printed.
PROCESS GRAPH	Graphic display of the harvest process.
USER ID	The name of the user that was logged into the software when the data was downloaded.

DATA TRANSFER TIME	The date and time when the download occurred.
CONTROL MODULE	The ID of the Control Module used for the harvest process.
CENTRIFUGE	The serial number of the centrifuge used for the harvest process.
DC LOT	The lot number of the Disposable Cartridge used for the harvest process.
DC EXPIRATION DATE	The Disposable Cartridge lot expiration date.
USER NOTES	An area to add comments to the processing record. A **SAVE USER NOTE** button appears after initial entry. Click **SAVE USER NOTE** to retain the comment.
DEPLETION VALVE OPEN DURATION	The time in seconds that depletion valve was open during the process.
HARVEST VALVE OPEN DURATION	Not applicable during WashPRO processes.
HARVEST TARGET VOLUME	The target harvest volume.
TEMPERATURE (C):	The minimum, average, and maximum temperatures that occurred within the centrifuge during processing.
GRAPH REVIEWED STATUS	Dropdown menu where the Lab Supervisor can provide an electronic review / signature of the processing report.

Preferences Section

The **PREFERENCES** section allows the Lab Supervisor and Lab Technician User to configure the software as indicated below. The software is configurable to each user's designated choices. Click the **SUBMIT EDIT** button to accept the entry or the **CANCEL** button to cancel the entry.



Automatic Logout

Includes a **LOG OUT AFTER INACTIVITY** checkbox and an up / down selection menu to configure a timeout from 10 to 500 minutes in 10-minute increments.

Starting top level item

Includes selection buttons to select the opening display screen (**HISTORY** or **PROCESS**).

Download Preferences

Includes checkbox to show report after download. Select to the checkbox to activate the option.

Password

Includes the following entry fields for changing a login password: **OLD PASSWORD**, **NEW PASSWORD**, and **CONFIRM NEW PASSWORD**.

Starting device

Includes selection buttons for the device to be opened upon login (Control Module or CryoPRO Workstation).

Expiration and maintenance warning

Includes up and down keys and dropdown menu selection to designate the amount of advance notification of expiration and calibration due dates in days, weeks, or months.

Section 4: Operating Instructions - System Set Up

SynGen™ Docking Station

Handle the SynGen™ Docking Station with care.

2. Plug in the USB cable into the USB port of the Docking Station and the USB port of the host computer or USB hub if applicable.
3. Plug power cord into Docking Station and then into the appropriate electrical outlet.
4. Verify the **POWER STATUS INDICATOR** is lit (red), and place a Control Module on the Docking Station. The **POWER STATUS INDICATOR** will turn green upon successful connection between the Docking Station and the Control Module.

WashPRO™ Control Module

The WashPRO™ Control Module battery should be charged in the SynGen™ Docking Station overnight or for at least 6 hours prior to initial use.

1. Place the Control Module onto a Docking Station that is plugged into an electrical outlet.
2. Verify that the Docking Station **POWER STATUS INDICATOR** is green.
3. Leave the Control Module charging in the Docking Station until the Control Module **BATTERY LED INDICATOR** remains green without blinking.

SynGen™ DataTrak Software

Ensure that the computer is virus-free and has the latest update of the antivirus software prior to the SynGen™ DataTrak Software installation.

Update the operating system, service pack, and antivirus software on a regular basis.

Do not leave the internet active while installing or using the DataTrak Software.

1. Verify that the computer meets the DataTrak Software requirements.
2. Verify that all updates have been completed.
3. Ensure that administrator access is available. The software will be installed by a SynGen Inc. technical representative.
4. The users, components of the WashPRO™ System, centrifuges and must be entered into the software before processing data can be downloaded. Follow the directions described in the Operating Instruction DataTrak Administration section to prepare the software.
    - If not already completed, attach the associated WashPRO System components to the host computer via the USB ports or USB hub (e.g., the Docking Station and / or barcode scanner).

Initial Login

The DataTrak software is programmed with a default name and password for the Administrator profile and default passwords for Lab Supervisors and Lab Technicians profiles to allow initial access to the software. The login will require the default name and password for Administrators and the default password for Lab Supervisors and Lab Technicians.

USER PROFILE	USER ID	PASSWORD
Administrator	admin	Admin-1
Lab Supervisor	Assigned by Administrator	Supervisor-1
Lab Technician	Assigned by Administrator	Technician-1

***NOTE**: User names and passwords are case sensitive.*

1. Launch DataTrak software by double clicking the icon located on the desktop.
2. In the User ID and password fields, enter the User ID: "admin" and default password, "Admin-1".
3. Click the **SUBMIT** button.
4. If the User ID and/or password is entered incorrectly, an "Unknown username or incorrect password" error will occur. Click the **CLEAR** button to clear the entries. Re-enter the correct User ID and password, then click the **SUBMIT** button.
5. The password should be changed once initial login is accomplished. Refer to the **Setting Preferences** section to change the password.
6. A new user must be set up as a Supervisor or Lab Technician in order to be able to access the **OPERATION** mode of the software.

Section 5: Operating Instructions: SynGen™ DataTrak Administration Mode

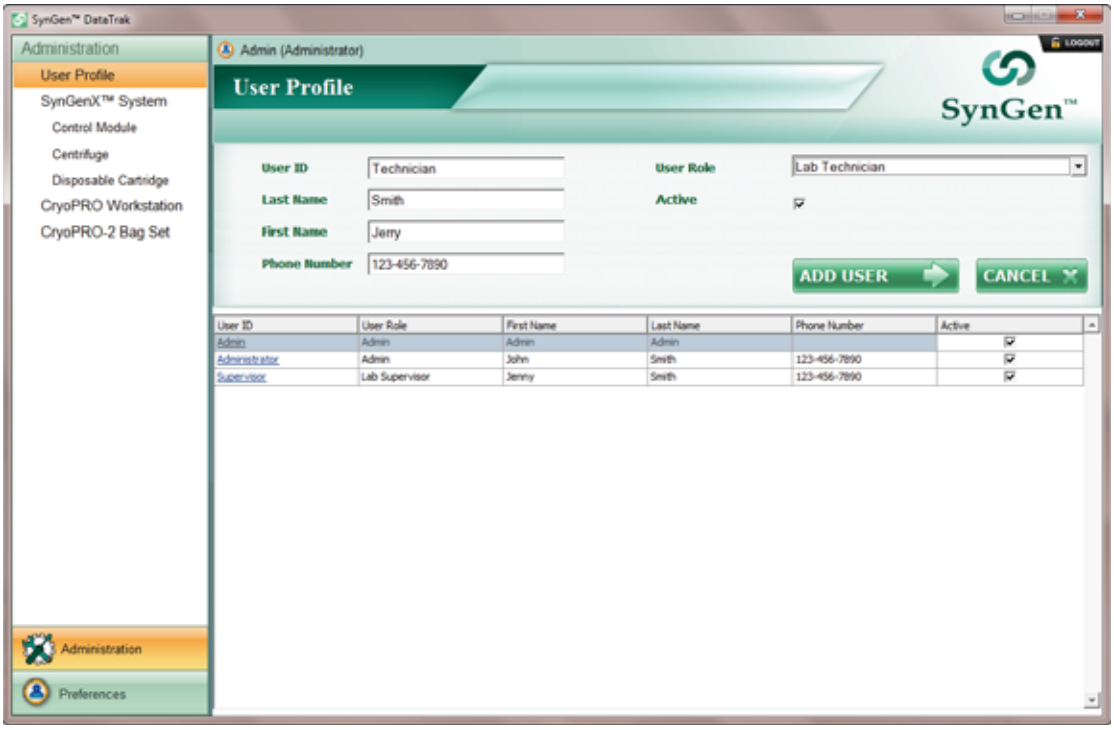
Only users with Administrator roles can access the **ADMINISTRATION** mode of the software. Verify all data entries prior to submitting, as they cannot be edited once accepted by the software. Exit the software completely once any entry field has been submitted or edited.

Software Login

1. Double click the **SYNGEN™ DATATRAK** icon located on the desktop to launch the software.
2. Enter **ADMINISTRATOR USER ID**, the associated password, and click the **SUBMIT** button.
3. If the User ID was entered incorrectly, an "Invalid User ID" error will occur. If the password is entered incorrectly, a "Password is incorrect" error will occur. Select **CLEAR** to clear both entries, ensure the user ID and password are correct, then click the **SUBMIT** button.

Adding and Editing a User

1. Verify **USER PROFILE** section on the left pane is highlighted. Enter the appropriate information into the **USER PROFILE** fields.



2. Select the applicable User Role using the dropdown menu.
3. Verify the **ACTIVE** checkbox is checked.
4. Click the **ADD USER** button to enter the user or the **CANCEL** button to clear the information.
5. A successful entry will display "User saved successfully".

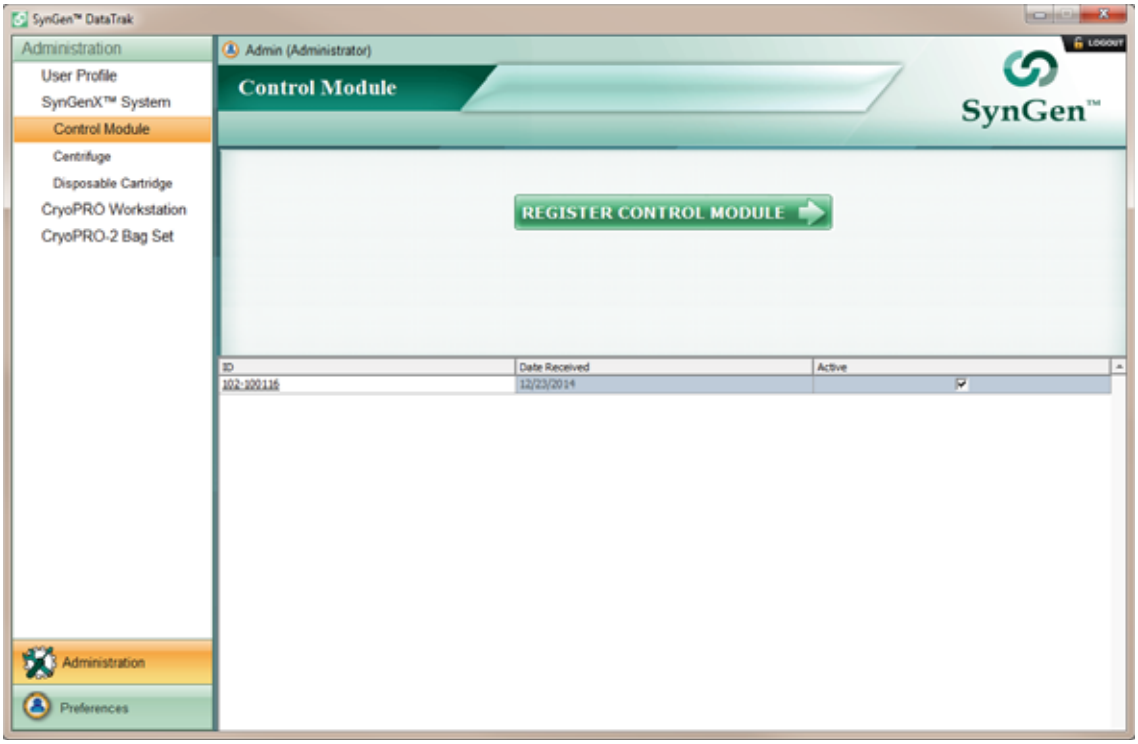
6. New users will be required to log in the first time using the default password. The password may be changed in the **PREFERENCES** section of the software after initial login.
7. Default password for Administrator is “Admin-1”.
8. Default password for Lab Supervisor is “Supervisor-1”.
9. Default password Lab Technician is “Technician-1”.
10. To edit a User Profile, click the appropriate name under the User ID column.
11. The corresponding information will appear in the entry fields and can be edited *except for the User ID*.
12. Unchecking the **ACTIVE** checkbox will inactivate the user. Inactive users will be unable to log in to the DataTrak software.
13. To save changes, click the **SUBMIT EDIT** button or click the **CANCEL** button to cancel all changes made.

Resetting a Password

1. Only default passwords are stored, to reset a password, click the appropriate name under the **USER ID** column.
2. Click the **RESET PASSWORD** checkbox.
3. Click the **SUBMIT EDIT** button to reset the password to the default setting or click the **CANCEL** button to cancel the edit.

Registering and Editing a WashPRO™ Control Module

1. Place an unregistered Control Module into a SynGenX™ Docking Station that is connected to the computer.
2. Click the **CONTROL MODULE** on the left navigation pane.

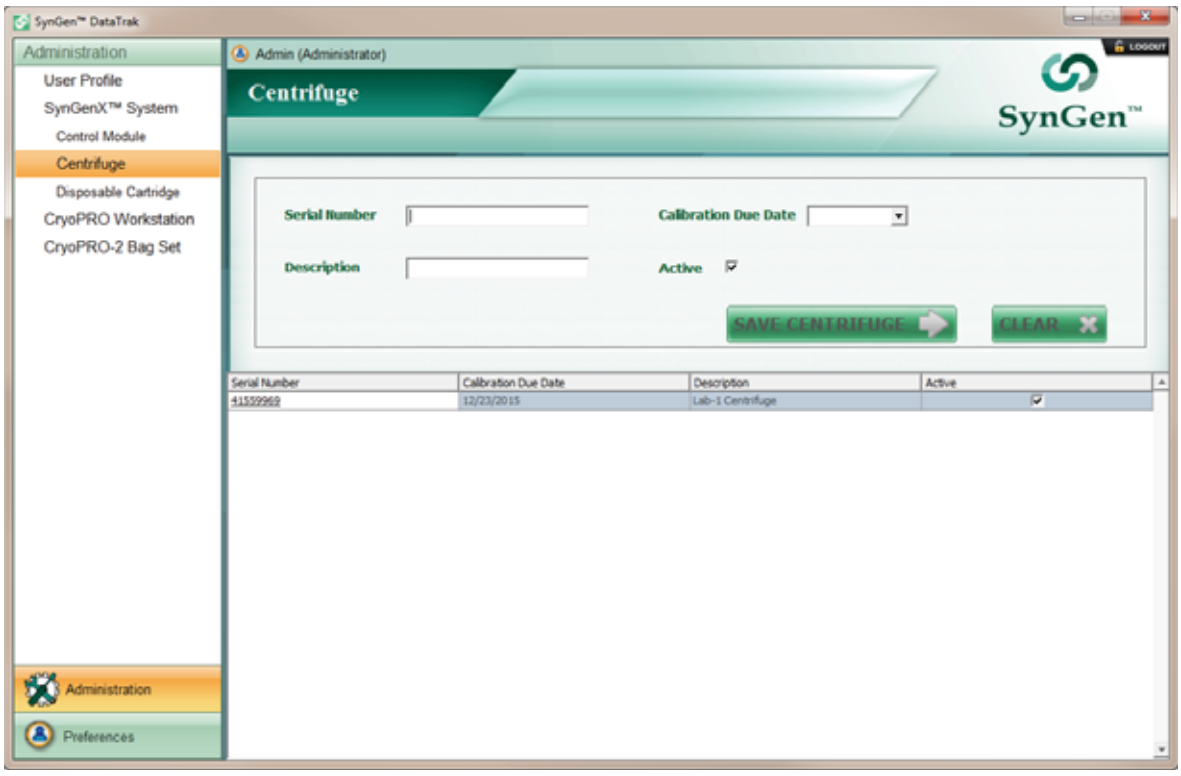


3. Click the **REGISTER CONTROL MODULE** button.

4. The **REGISTER CONTROL MODULE** window will appear. Scan or type the serial number of the Control Module and select the received date from the dropdown menu. The default will be the current date.
5. Click the **REGISTER** button to register the Control Module. Click the **CANCEL** button to exit without registering.
6. Verify the Control Module information displayed in the table.
7. To inactivate a Control Module, click the ID of the appropriate Control Module in the table.
8. The Control Module edit fields will appear. Only the **ACTIVE STATUS** and the **LAST MAINTENANCE** fields may be edited.
9. Click the **ACTIVE** checkbox to uncheck. Inactive Control Modules will not be recognized for data download.
10. Click the **SUBMIT EDIT** button to inactivate or click the **CANCEL** button to cancel the edit.
11. To return a Control Module into use after maintenance, click the ID of the appropriate Control Module in the table.
12. Click the **ACTIVE** checkbox and then select the **LAST MAINTENANCE** date from the dropdown menu.
13. Click the **SUBMIT EDIT** button to activate the Control Module or click the **CANCEL** button to cancel the edit.

Adding and Inactivating a Centrifuge

1. Click **CENTRIFUGE** on the left navigation pane.

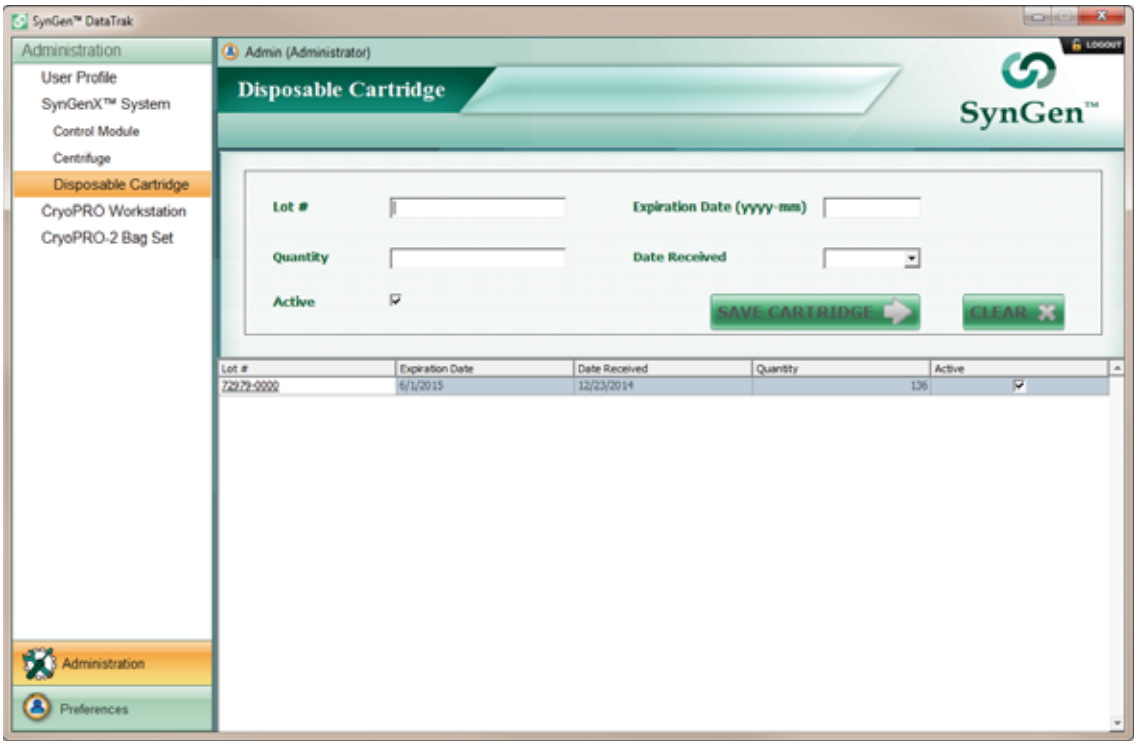


2. Enter the **SERIAL NUMBER** and **DESCRIPTION** (optional).

3. Select the **CALIBRATION DUE DATE** from the dropdown menu. The software will not accept calibration due dates in the past.
4. The **ACTIVE** button default is checked—to inactivate, click the **ACTIVE** checkbox.
5. Click the **SAVE CENTRIFUGE** button to save the centrifuge information or the **CLEAR** button to clear the entry.
6. Verify Centrifuge information is displayed in the table.
7. To make the Centrifuge inactive, click the appropriate **SERIAL NUMBER** of the centrifuge in the table.
8. Click the **ACTIVE** checkbox to uncheck. Inactive Centrifuges will not appear in the download dropdown menu option.
9. To save the change, click the **SAVE CENTRIFUGE** button or click the **CLEAR** button to clear the change.

Adding and Editing a SynGenX™-WASH Disposable Set

1. Click **DISPOSABLE CARTRIDGE** on the left navigation pane.

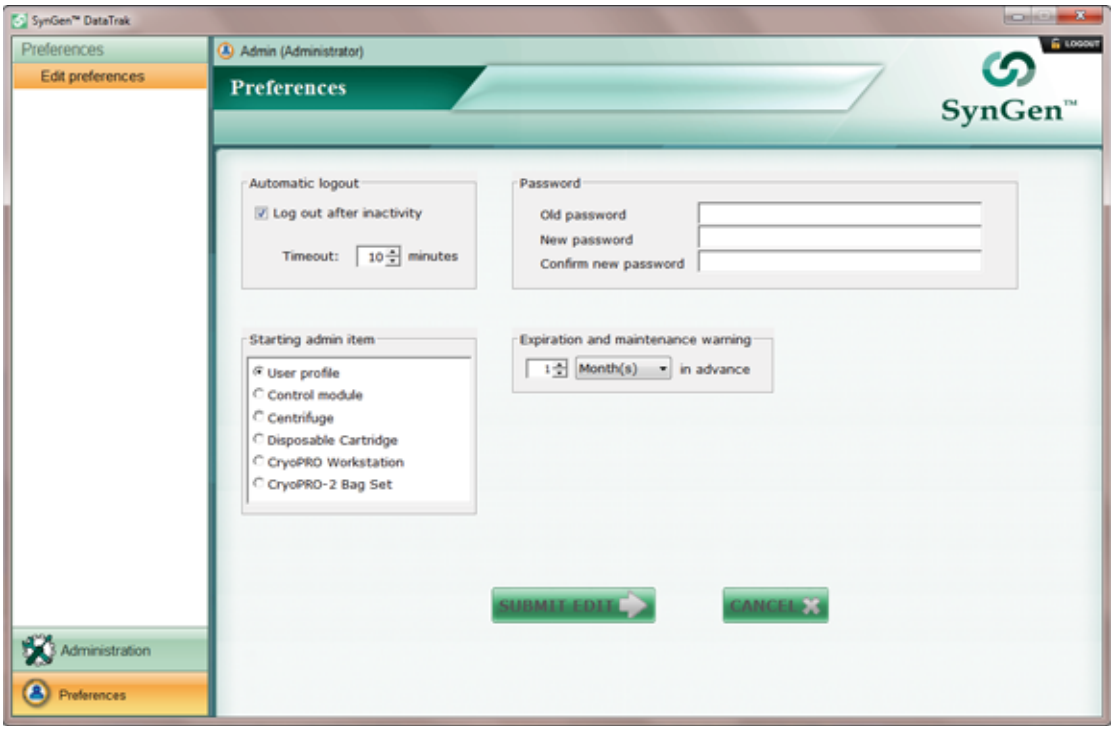


***NOTE**: Alpha version SynGenX™-WASH Disposable Sets may or may not have lot numbers. If no lot number is published on a sticker on the Cartridge Set, this will not be trackable in the SynGen™ DataTrak Software.*

2. Enter the **LOT#**, **QUANTITY**, **ACTIVE** status, **EXPIRATION DATE** in the format yyyy-mm, and the **DATE RECEIVED** from the dropdown menu.
3. The software will not accept an expiration date in the past or a date received in the future. An expired lot will not be available for download and will not appear in the **DOWNLOAD** dropdown menu.
4. Click the **SAVE CARTRIDGE** button to save the Disposable Cartridge information or the **CLEAR** button to clear the entry.
5. Verify the Disposable Cartridge information is displayed in the table.
6. Only the quantity and active status may be edited once the Disposable Cartridge information has been entered. Click the appropriate lot number to display the edit fields.
7. Unchecking the **ACTIVE** checkbox will inactivate the lot number. Inactive lot numbers will not appear in the **DOWNLOAD** dropdown menu option.
8. Enter the quantity in the **QUANTITY** field as applicable.
9. To save changes, click the **SAVE CARTRIDGE** button or the **CLEAR** button to clear all changes made.

Editing Preferences

1. Click the **PREFERENCES** section on the lower left navigation pane.
2. The **PREFERENCES** window will appear.



3. Click the **AUTOMATIC LOGOUT** checkbox and select the appropriate time in minutes from the dropdown menu.

4. Select the **STARTING ADMIN** item from the options displayed. The selected item will automatically appear upon after logging into the software.
5. Set the **EXPIRATION** and **MAINTENANCE WARNING** up / down keys to set the number and the dropdown menu for the days, weeks, or months.
6. To edit a password, enter the current password, the new password and confirm the new password by reentry of the new password. The password must be between 8 and 20 characters and must include one number and one punctuation character.
7. Click the **SUBMIT EDIT** button to save the changes or the **CANCEL** button to cancel all changes made.

Exiting Administration Mode

1. To exit the DataTrak System **ADMINISTRATION** mode, click the **LOGOUT** icon in the upper right corner to return you to the initial login screen.
2. To exit the software completely, click the red **X** in the upper right section of the window.

Section 6: Operating Instructions SynGen™ DataTrak Operations Mode

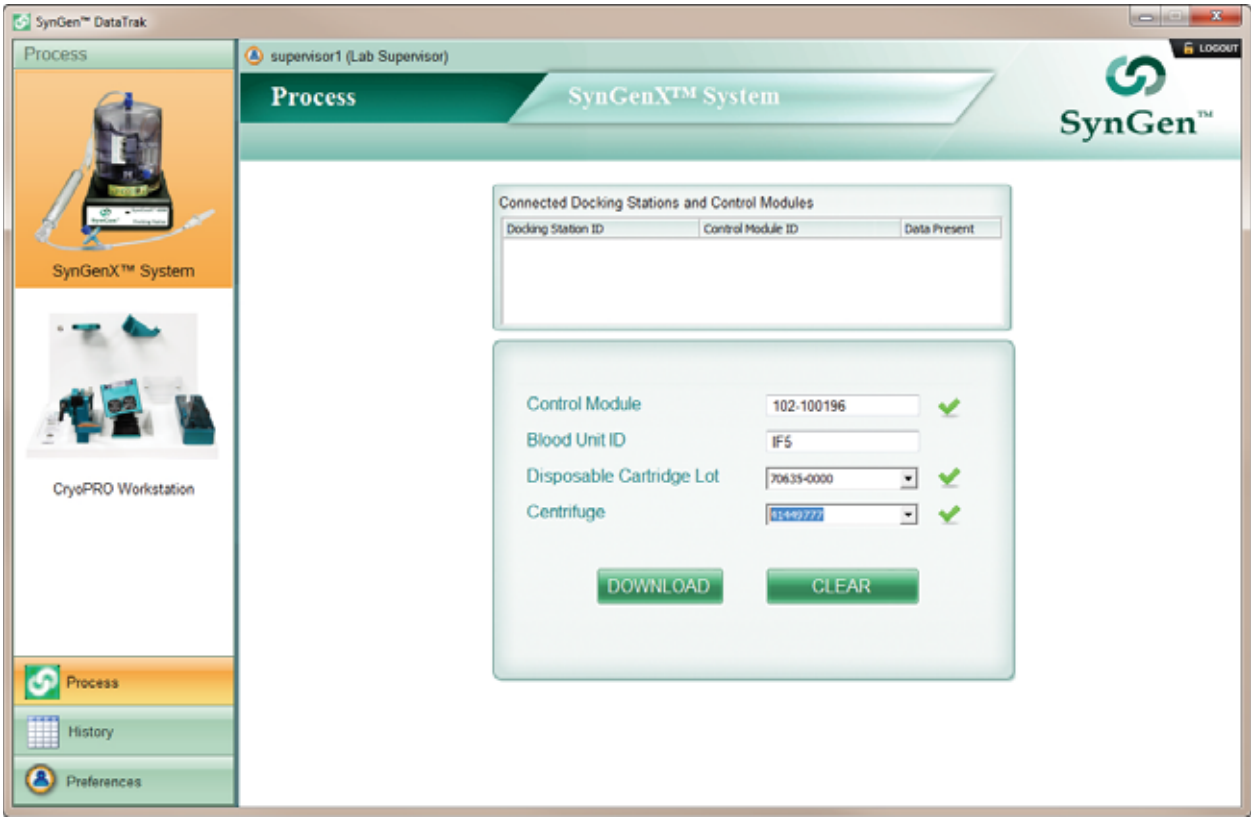
Logging In

1. Double click the **DATATRAK ICON** located on the desktop to launch the software.

2. Enter the appropriate **USER ID** and **PASSWORD**.
3. Click the **SUBMIT** button.
4. If the User ID and/or Password are entered incorrectly, an "Unknown username or incorrect password" error will occur. Click the **CLEAR** button to clear the entries. Re-enter the correct User ID and password, then click the **SUBMIT** button.

Downloading WashPRO™ Control Module Data

1. Verify that the SynGenX™ Docking Station is connected to the computer via the USB cable.
2. Click the **SYNGENX™ SYSTEM** icon on the left navigation pane.
3. Place the Control Module in the Docking Station per instructions for use.
4. Scan barcode or enter the Control Module serial number and **BLOOD UNIT ID**.
5. Select the appropriate WashPRO™ **DISPOSABLE CARTRIDGE LOT** and **CENTRIFUGE** serial number from the dropdown menu.
6. A green checkmark will indicate an acceptable entry a red "X" will indicate an unacceptable entry. Verify information associated with a red "X" and re-enter as appropriate.



7. Click the **DOWNLOAD** button to download the data located on the Control Module or the **CLEAR** button to clear the fields.

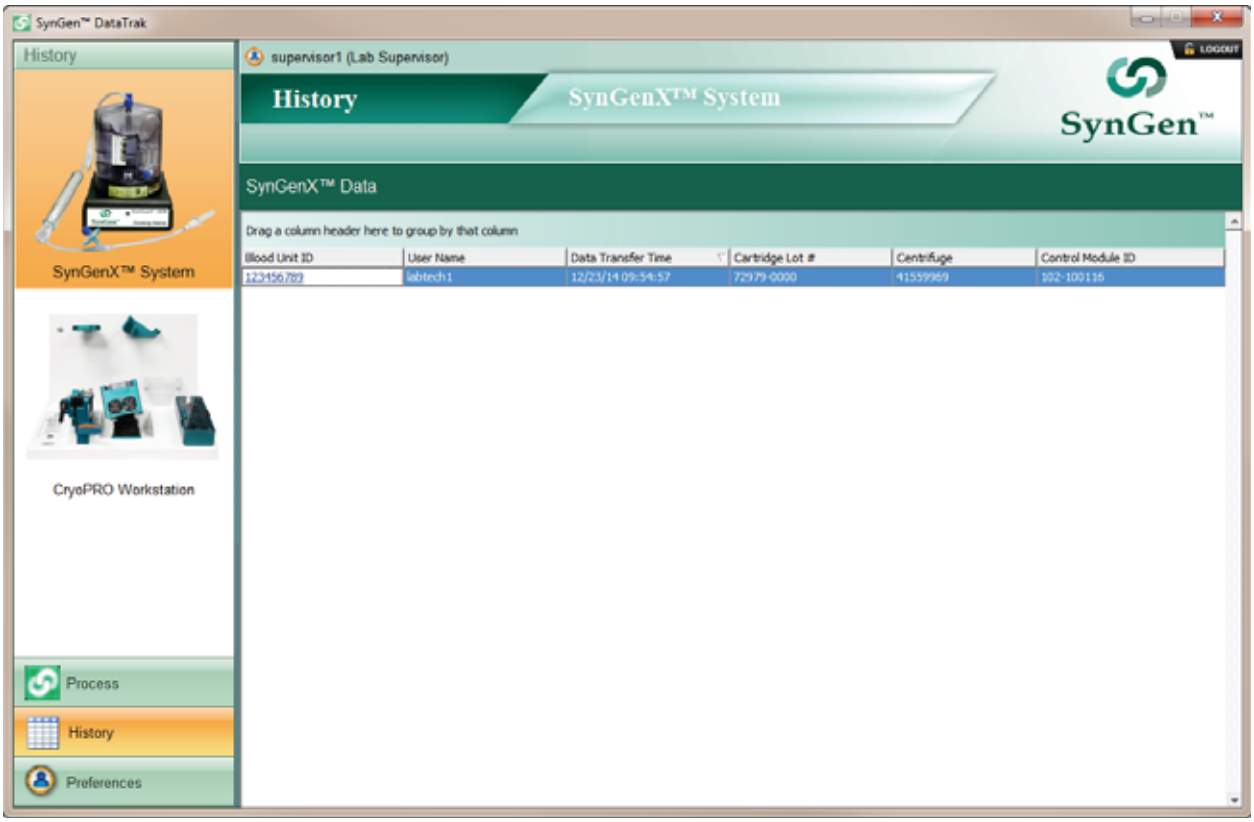
Processing Reports

The mechanisms to view processing reports, which are the output of the data downloaded from the Control Module.

- Access the report through the **HISTORY** section.
- Configure the report to launch upon download.

Accessing the History Section

1. Click the appropriate icon (e.g., **SYNGENX™ SYSTEM**) on the left navigation pane to highlight.
2. Click **HISTORY** on the lower left navigation pane.



3. Click the **BLOOD UNIT ID** of the report to be viewed. The report is displayed in a new window.

Launch Report on Download

1. Click the **PREFERENCE** section on the lower left navigation pane.
2. Check the checkbox next to **SHOW REPORT AFTER DOWNLOAD** under **DOWNLOAD PREFERENCES** area.
3. Click the **SUBMIT EDIT** button to save the change.
4. The report will now be displayed automatically after each download.

Adding User Notes

1. To add comments to the report, place the cursor in the **USER NOTES** field.
2. Enter comments, a **SAVE USER NOTE** button appears after initial entry.
3. Click the **SAVE USER NOTE** button to retain the comment. The comment is documented with the date/time and logged-in user for each entry saved.

Saving or Printing the File

1. To save the processing report as a PDF file, click the **SAVE AS PDF** button.
2. Select the file location and edit the file name as needed.
3. Click the **SAVE** button.

4. To print the processing report, click the **PRINT** button.
5. Verify printer and click the **PRINT** button.

Export

1. To export the processing report as a CSV file, click the **EXPORT** button.
2. Select the file location and edit the file name as needed.
3. Click the **SAVE** button.

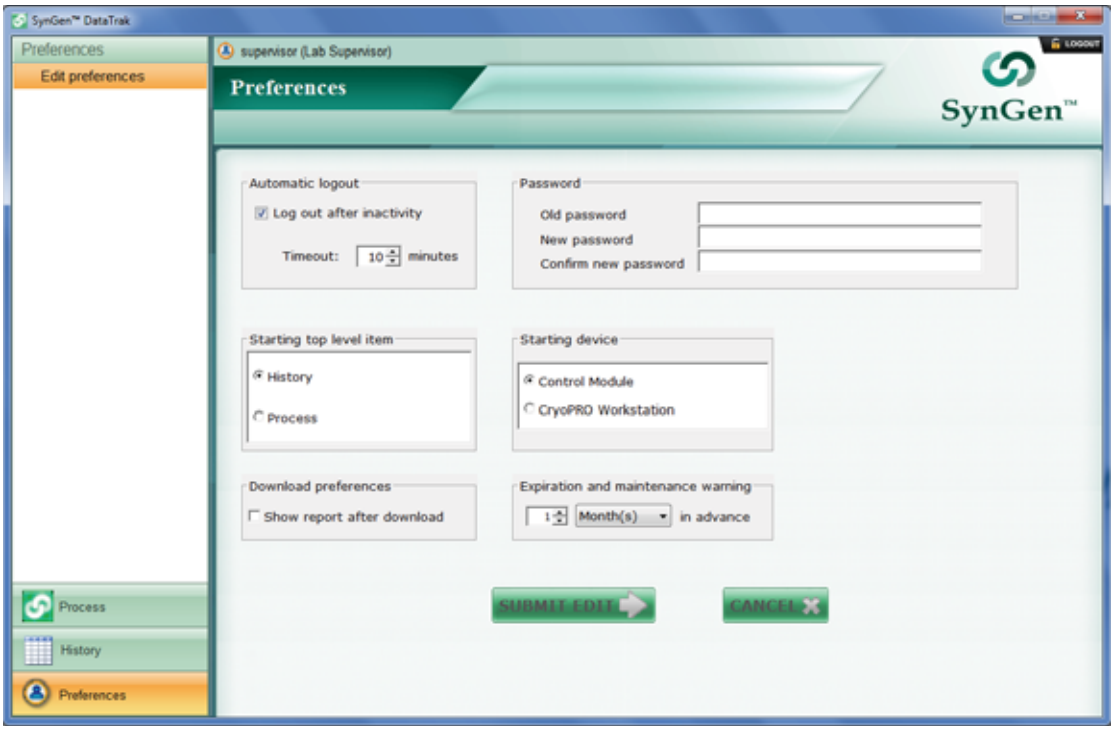
Reviewing the Report

Only a Lab Supervisor may add a "Graph Reviewed By" signature to a processing report.

1. Click the dropdown menu **GRAPH REVIEWED BY** and select the username.
2. To save the processing report as a PDF file, the **SAVE AS PDF** button.
3. Select the file location and edit the file name as needed.
4. Click the **SAVE** button.
5. To print the processing report, click the **PRINT** button.
6. Verify the printer and click the **PRINT** button.

Setting Preferences

1. Click the **PREFERENCES** section on the lower left navigation pane.
2. The **PREFERENCES** window will appear.



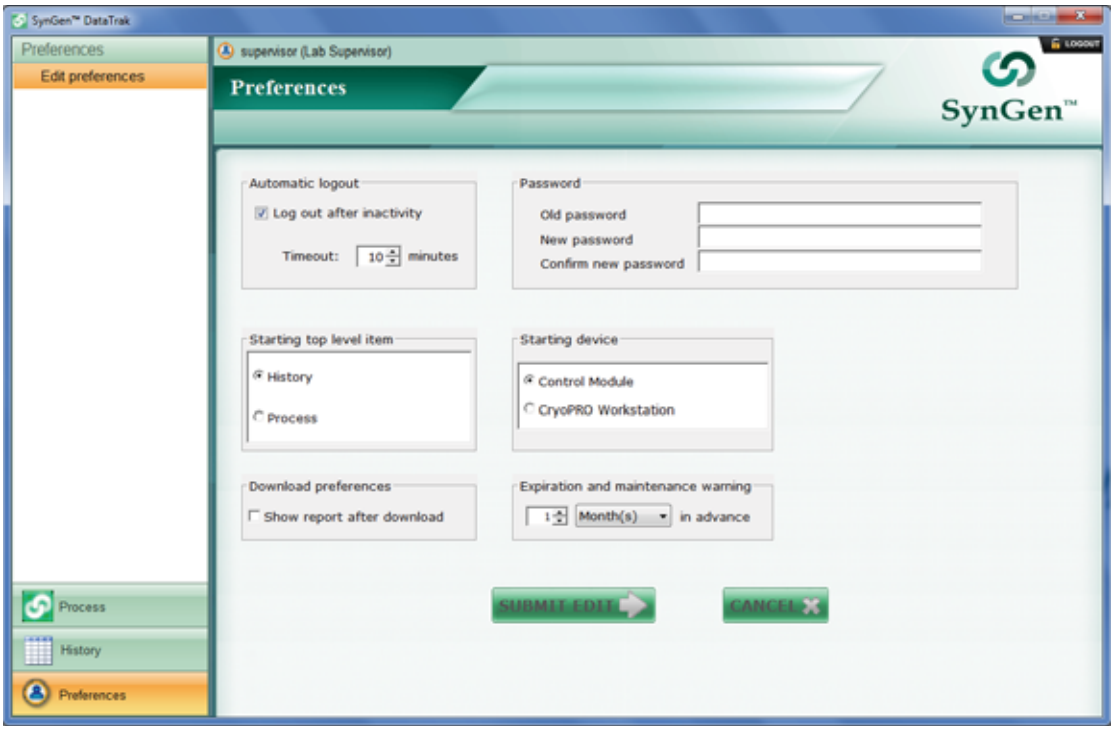
3. Click the **AUTOMATIC LOGOUT CHECKBOX** and select the appropriate time in minutes from the dropdown menu.
4. Select the **STARTING TOP-LEVEL ITEM** from the options displayed. The selection will automatically appear upon after logging into the software.
5. Click the **SHOW REPORT AFTER DOWNLOAD** checkbox to either enable or disable.
6. To edit a password, enter the current password, the new password and confirm the new password by reentry.

Password must be between 8 and 20 characters and must include one number and one punctuation character.

7. Select the **STARTING DEVICE** from the options displayed. The selection will automatically appear upon after logging into the software.
8. Set the **EXPIRATION** and **CALIBRATION** warning using the dropdown menu for days, weeks, or months.
9. Click the **SUBMIT EDIT** button to save the changes or the **CANCEL** button to cancel all changes made.

Logging Out & Exiting

1. To log out from the DataTrak program, select **LOGOUT** in the upper right corner to return you to the initial login screen.



2. To exit out of the DataTrak program, close the window by selecting the red "X" icon on the upper right side of the window.

Section 7: Operating Instructions: WashPRO™ System

It is strongly recommended that users review the entire manual and operating instructions prior to initial system use.

Follow aseptic procedures.

Operators should be trained on the WashPRO™ System prior to initial use.

Acceptable Processing Volume

The WashPRO™ System is intended to process cell cultures with volumes between 40 mL and 480 mL in a single wash cycle.

Equipment, Materials, and Reagents

Equipment:

- Two WashPRO™ Control Modules
- SynGen™ Docking Station
- Sterile Connection Device (for closed system processing)
- Biological Safety Cabinet (if applicable)
- Thermo Scientific Sorvall™ Legend™ XT or XTR centrifuge or equivalent
- Customized Centifuge Hub for Tubing Management
- Cord Blood Unit ID Label Generator
- Digital Scale
- Tube Sealer
- Computer with SynGen™ DataTrak Software and WashPRO™ Software
- Waste Container
- 1 kg Calibrated Weight

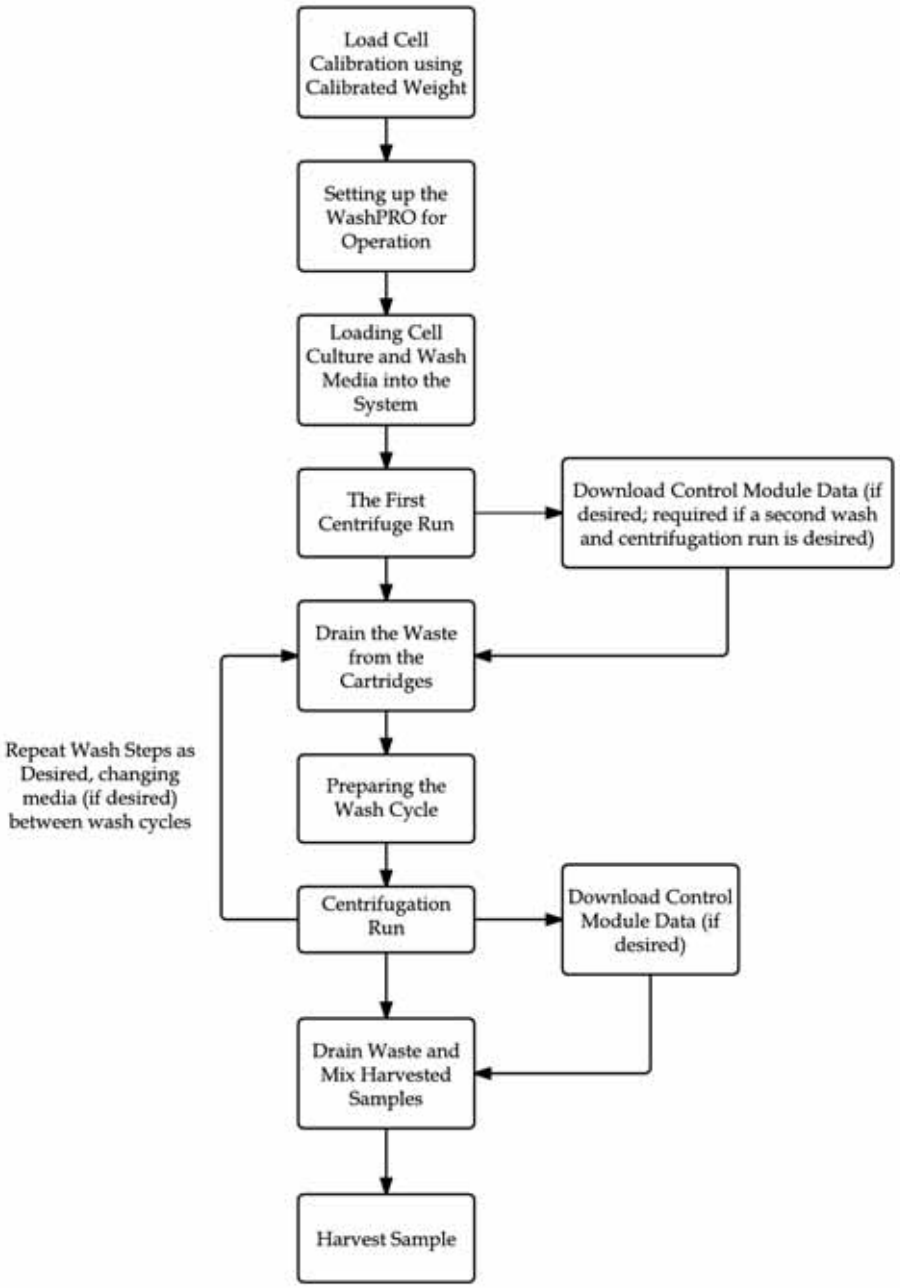
Materials:

- SynGenX™-WASH Disposable Set
- Labels
- Harvest bag

Reagents:

- Washing buffers (as many types as desired)

Process Flow

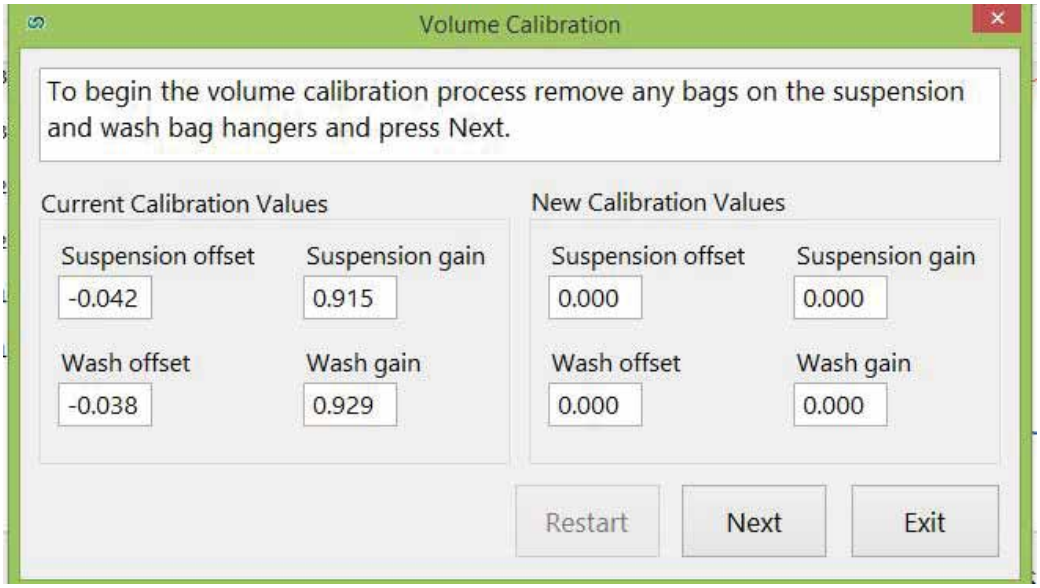

Load Cell Calibration using Calibrated Weight
Setting up the WashPRO for Operation
Loading Cell Culture and Wash Media into the System
The First Centrifuge Run
Download Control Module Data (if desired; required if a second wash and centrifugation run is desired)
Drain the Waste from the Cartridges
Repeat Wash Steps as Desired, changing media (if desired) between wash cycles
Preparing the Wash Cycle
Centrifugation Run
Download Control Module Data (if desired)
Drain Waste and Mix Harvested Samples
Harvest Sample

Setting up the WashPRO™ System for Operation

Calibrating the Load Cell

The Load Cells should be calibrated weekly to ensure accurate volume transfer during washing steps.

1. Power the WashPRO system on.
2. Power the computer on and launch the WashPRO™ Software using the **WASHPRO** icon on the desktop.
3. Remove any cell suspension bags, wash media bags, and SynGenX™-WASH Disposable Sets from the WashPRO™ Workstation.
4. Click **SETTINGS** at the top left corner of the screen and choose **CALIBRATE VOLUMES**.
5. Follow the instructions on the top of the Volume Calibration Window:



   a. Verify that nothing is on any of the load cell hooks.
      i. Click **NEXT**.
   b. Add a 1 kg standard weight to the cell suspension bag hanger.
      i. When the weight is no longer moving, click **NEXT**.
   c. Add a 1 kg standard weight to the diluent wash bag hanger.
      i. When the weight is no longer moving, click **NEXT**.
   d. Press **NEXT** to apply and save the calibration coefficients.
6. Remove the 1 kg weights from the load cell hooks.

Understanding Clamp Operation

It is critically important that there is familiarity in how the pinch clamps on the tubing sets work. Facing all clips in the same direction across the WashPRO Workstation and Disposable Sets will make it easier to operate the system.

Preparing the SynGenX™-WASH Disposable Set

Always follow established procedures for handling and disposing of biohazardous materials.

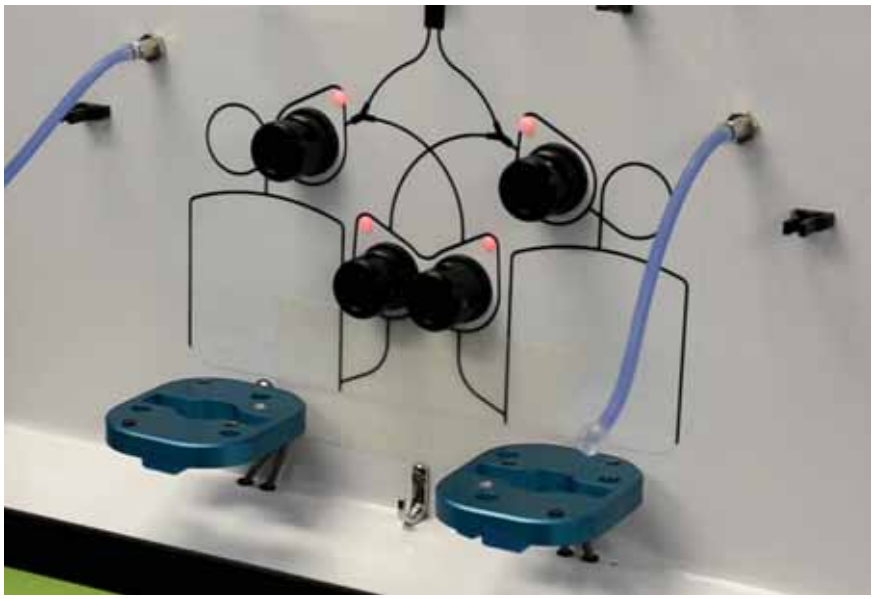
1. Remove the X-WASH Disposable Set from its packaging.
2. Visually inspect Disposable Set. Do not use any Disposable Set that has missing or damaged components.

3. Remove the pin from the bottom of the Cartridge.

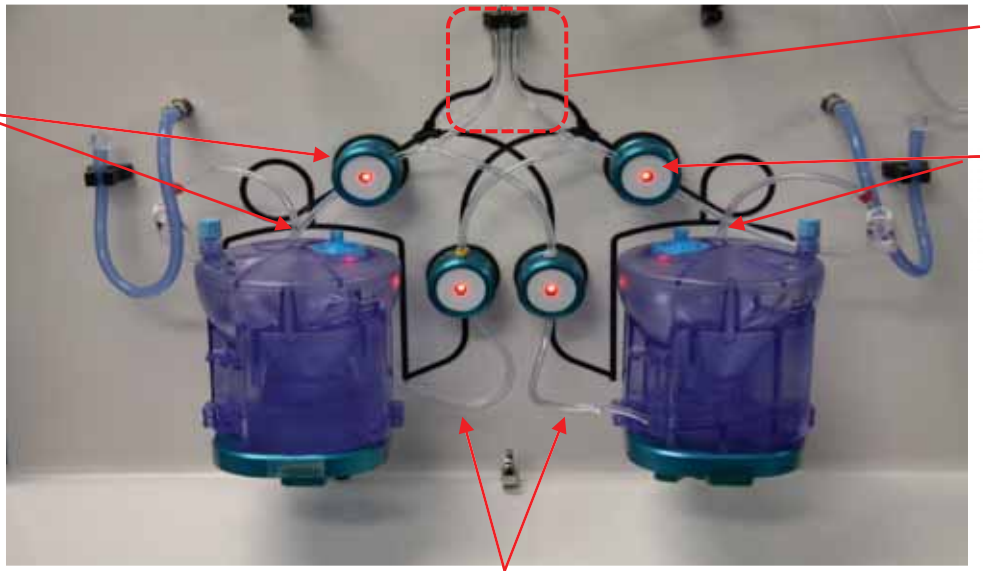
4. Remove caps from both air filters and discard.

Mounting the SynGenX™-WASH Disposable Set on the WashPRO™ Workstation

1. Locate the rotating holders on the front of the WashPRO Workstation.

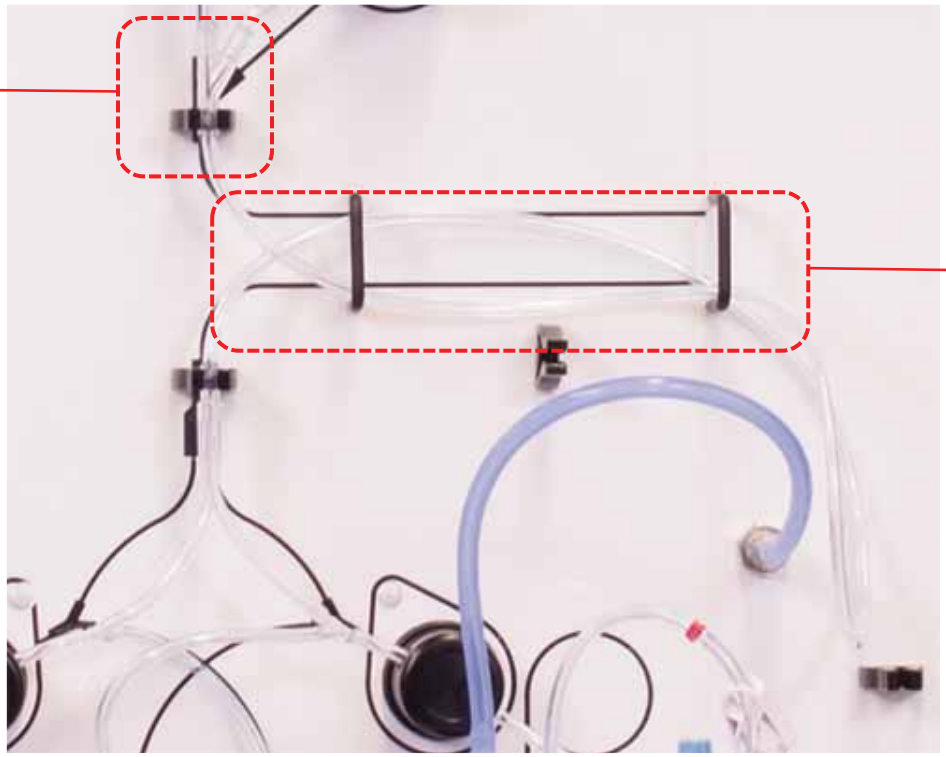


2. Place the Cartridges on the left and the right rotating holders.
3. Starting at the Cartridges, position the tubing in the pinch valves. The backdrop of the WashPRO Workstation shows where the tubing connects.

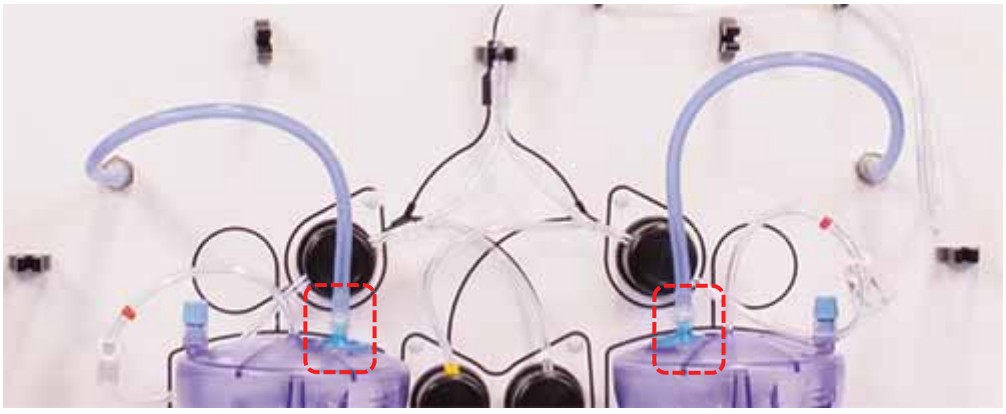

Central funnel tubing is placed in upper valve
Lower Y-Connector holder
Central funnel tubing is placed in upper valve
Harvest Chamber access tubing is placed in lower valves

4. The harvest chamber access tubes are placed into the lower valves.
5. The central funnel tubing is placed in the valves just above the Cartridge.
6. The Y-connector should be placed into lower Y-connector holder.

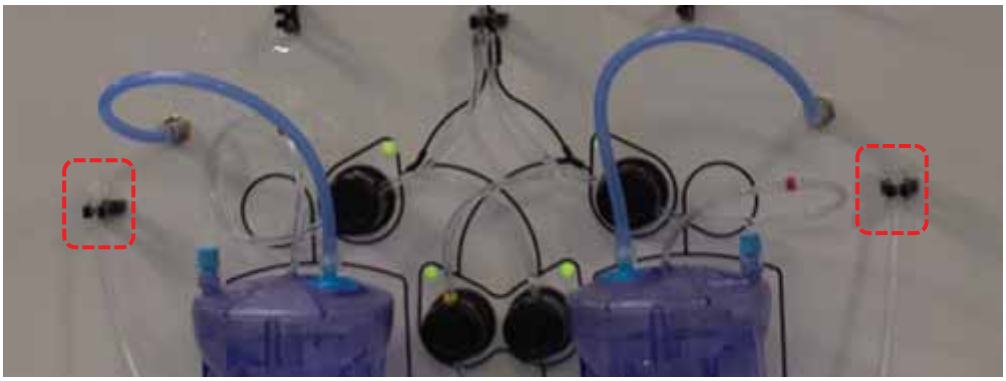
7. Place the Y-connector located below the media bag and cell culture bag tubing into the upper Y-connector holder. Route the extra tubing to the right through the tubing holder.



8. Connect the blue vacuum / pressure tubes to the air filters on the top of each Cartridge.



9. Place the waste line tubing coming from the waste bucket in the tube holders near the blue vacuum / pressure tubes. These are not used at this time.

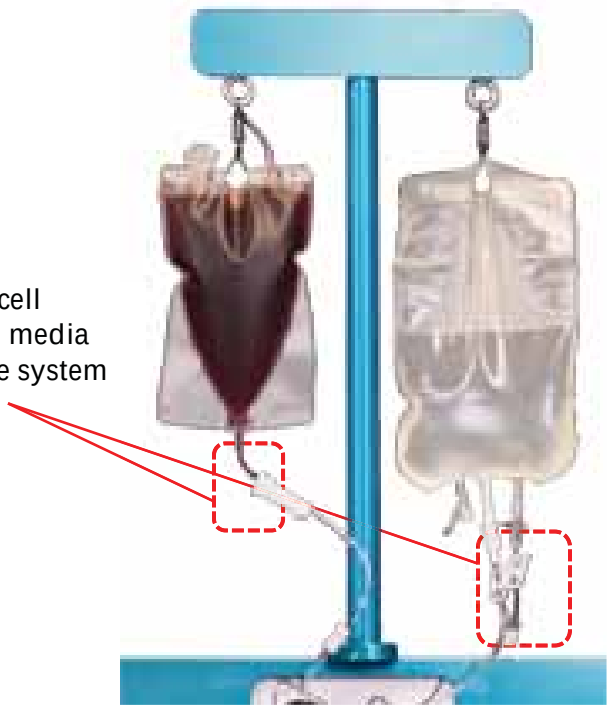


Preparing the Cell Culture and Wash Media

1. Prepare the bags of cell culture and wash media following lab best practices.
2. Locate the Y-Connector below the cell culture and wash media bags.
3. The clips on the tubing below the cell culture and wash media bags must be closed until the WashPRO Workstation valves are closed, as seen when the valve indicators are green.
4. Sterile dock / Spike the cell culture bag to the LEFT tube from the Y-Connector.
5. Sterile dock / Spike the wash media bag to the RIGHT tube from the Y-Connector.

***NOTE**: Sterile docking of the two bags to the Disposable Set can be completed prior to hanging the bags on the WashPRO Workstation. However, the clips on the input tubing must be clamped prior to docking.*

Close the clips below the cell suspension bag and wash media bag until the valves on the system are closed automatically.



6. Hang the cell culture bag from the left load cell hook.
7. Hang the wash media bag on the right load cell hook.

Verify the Centrifuge Programming

1. Select the centrifuge program that was established for the WashPRO protocol and verify that the program includes the following steps:
    a. 1000 g for 10 minutes
    b. 100 g for 1.5 minutes
    c. 1000 g for 1 minute
    d. 100 g for 1.5 minutes
    e. Stop following processing

***NOTE**: The above steps are the default program for the WashPRO System. These steps may differ or be customized depending on the end application, cell types, and preferences.*

Prepare the WashPRO™ Control Modules for Operation

1. Obtain a Control Module and press the **POWER** button.

Do not to insert any objects, including fingers, into the WashPRO Control Module while powering on.

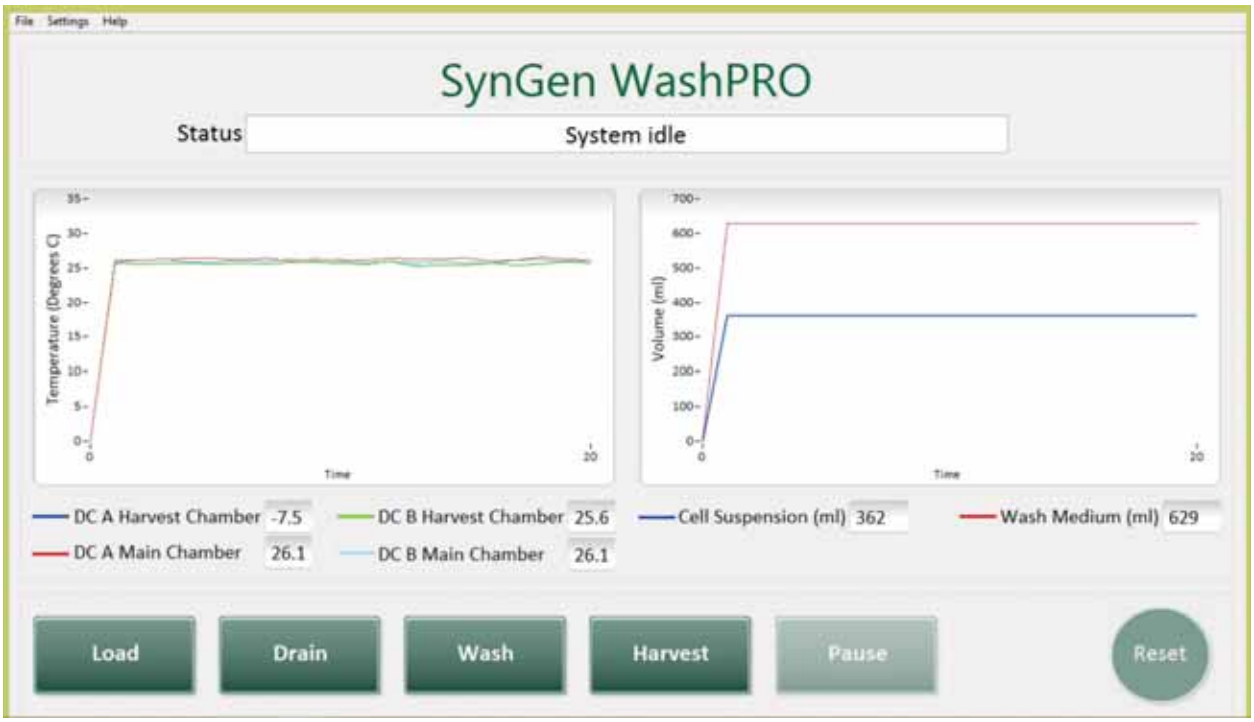
2. Verify the battery status indicator is green. If not, charge the Control Module.

- If there is any concern about the battery charge level, place the Control Module on the Docking Station. If the battery status indicator is:
    - Steady green or slow blinking green if the battery has a sufficient charge to perform a harvest process.
    - Steady red if the battery is insufficiently charged. The operator should immediately charge the battery.

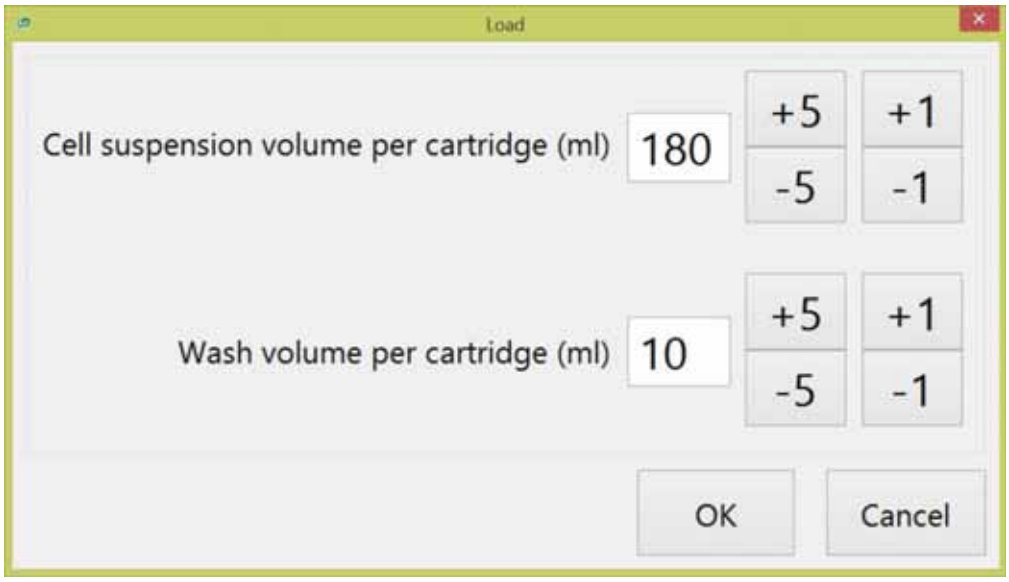
3. Verify that the status display is "0". If dP is displayed, download the data on the Control Module before proceeding.
4. If any other character is displayed, contact SynGen Customer Support.
5. Turn the Control Module off by pressing and holding the **POWER** button (approximately 3 seconds) until the display shows no lighted indicators.

Loading Cell Culture and Wash Media into the System

1. Open the WashPRO Software.



2. Select **LOAD** to launch the culture and media loading steps.



a. Enter the **CELL SUSPENSION VOLUME PER CARTRIDGE** in mL.

Note: The volume of the cell suspension per Cartridge must be between 40 mL and 240 mL.

b. Enter the **WASH VOLUME** of media to dispense into the harvest compartment of the Cartridge.

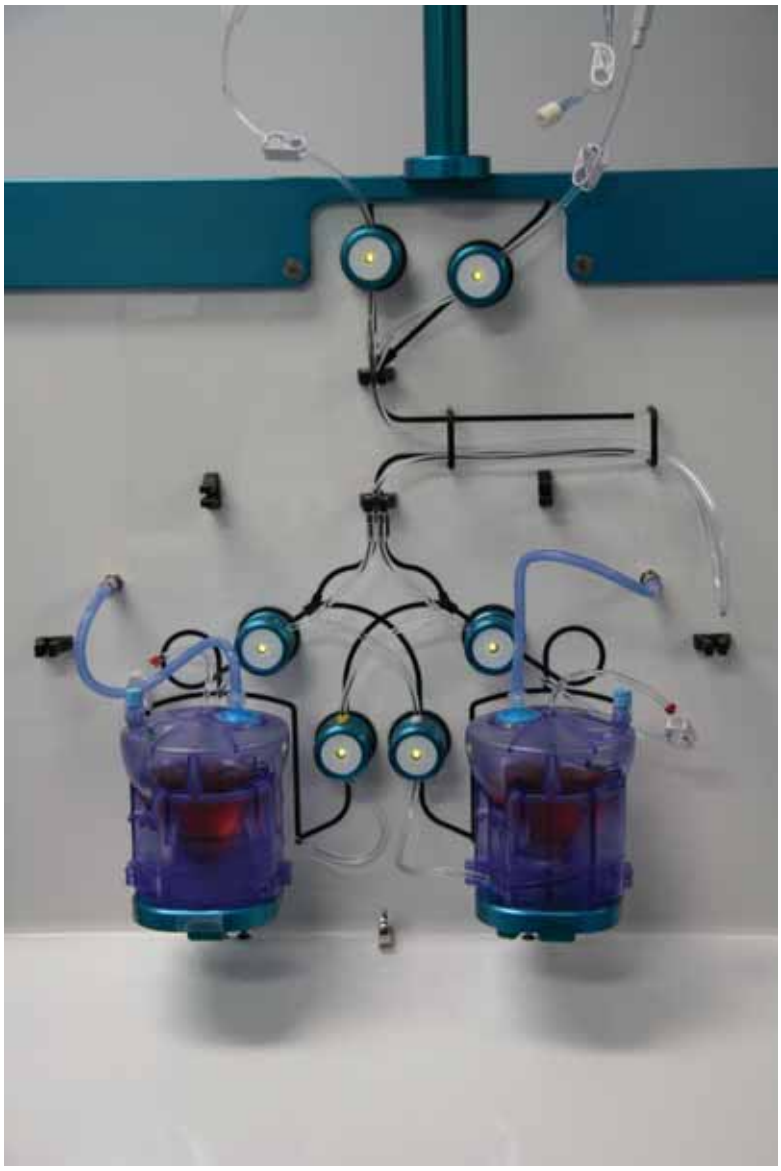
***NOTE**: This is the volume of fresh media the harvested cells will be resuspended in. Typical volumes range between 5 mL and 40 mL.*

3. Press **OK** when the volumes have been entered.
4. **Immediately open the clips** below both the cell culture bag and the new wash media bag.

***NOTE:** If you do not open the valves quickly enough, the volumes of liquid will not come out at an even rate.*

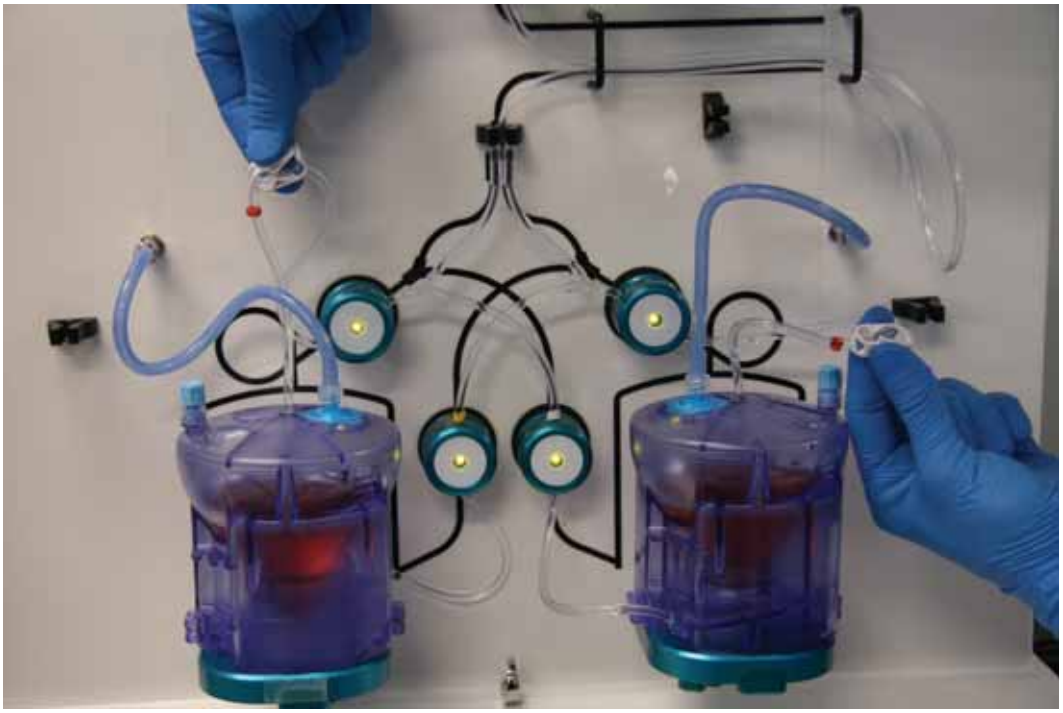
5. The WashPRO will automatically dispense the selected cell suspension volume to the central funnel compartment of each Disposable, along with the selected wash volume in the harvest compartment of each Disposable.

6. At the completion of the load process, all the valve indicators will illuminate green, indicating they are closed.



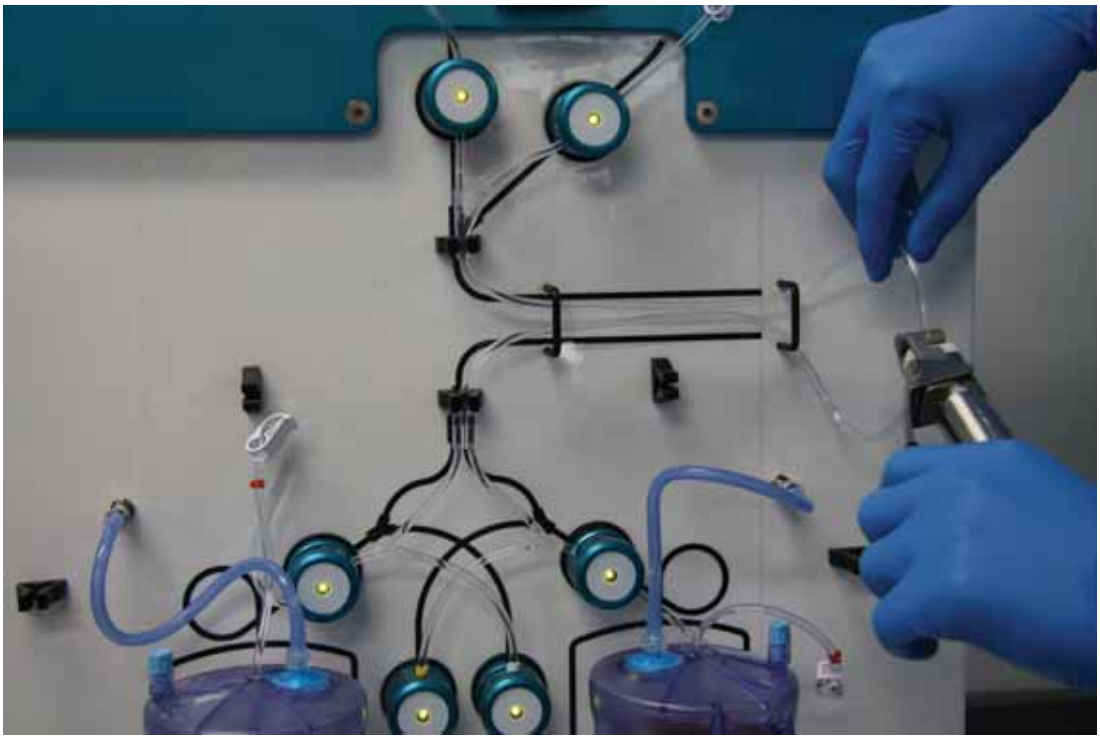
7. Manually close the tube clamps below the wash media and cell suspension bags.

8. Close the clamps on the central funnel tubes at the top of each Disposable.

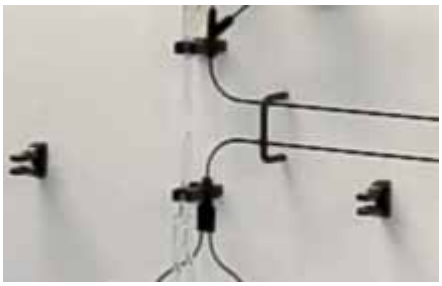


9. Place the harvest compartment access tubes in the slots on the side of the Disposable housings, ensuring they are tightly pinched and preventing fluid flow.

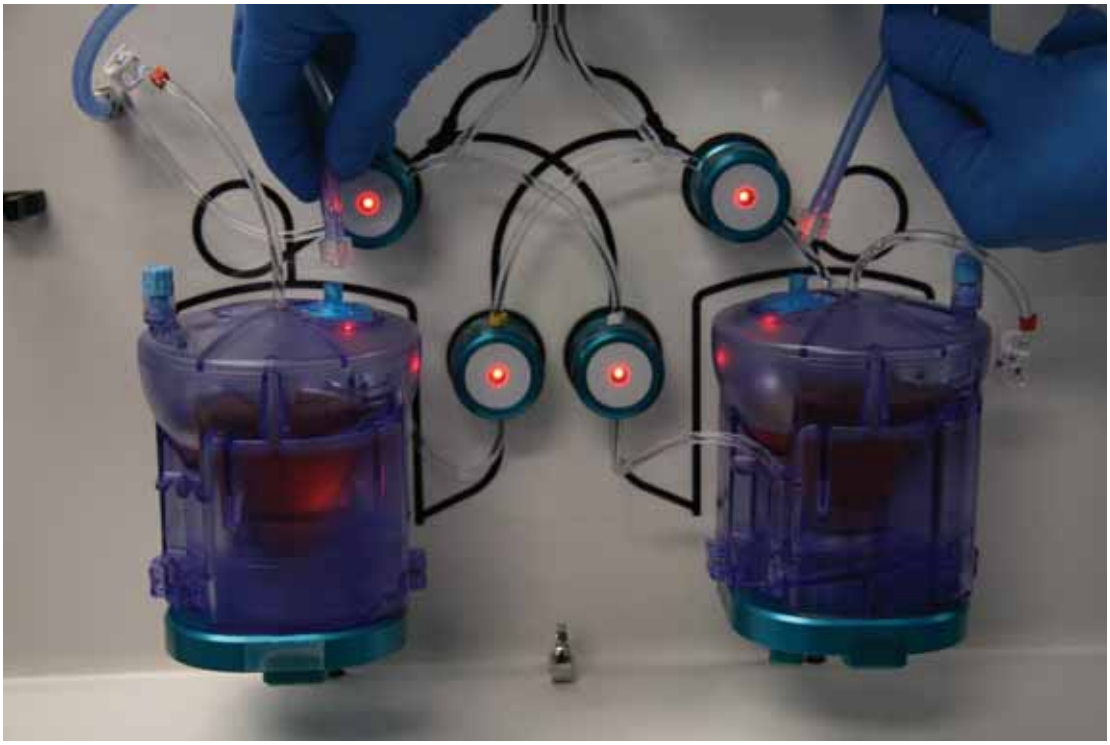
10. Using the tube sealer, seal the tubing between the two Y-Connectors.



11. Using scissors, carefully cut the sealed tubing.



12. Disconnect the blue vacuum / pressure tubes from the two Disposables.



13. Press the **RESET** button on the WashPRO Software and select **YES** to open the valves.

14. Carefully remove the tubing below the tube-seal from the WashPRO Workstation pinch valves.

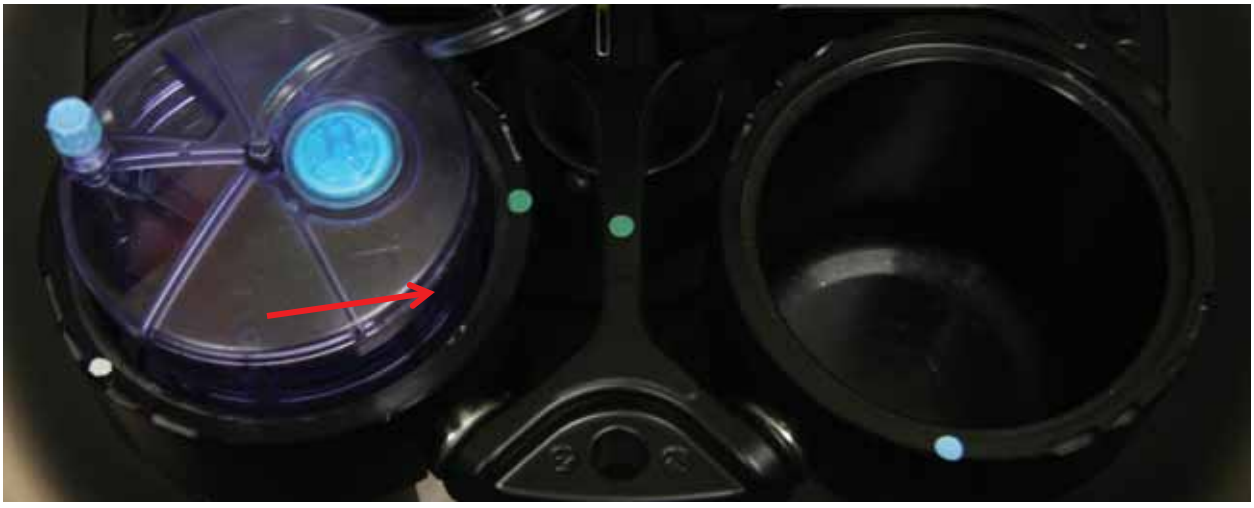
15. Remove the Disposables from the rotating holders by pressing on the release buttons on either side of the Disposable housings.

16. Attach the Disposable Set to two Control Modules.
17. Power on the Control Modules.

The First Centrifuge Run

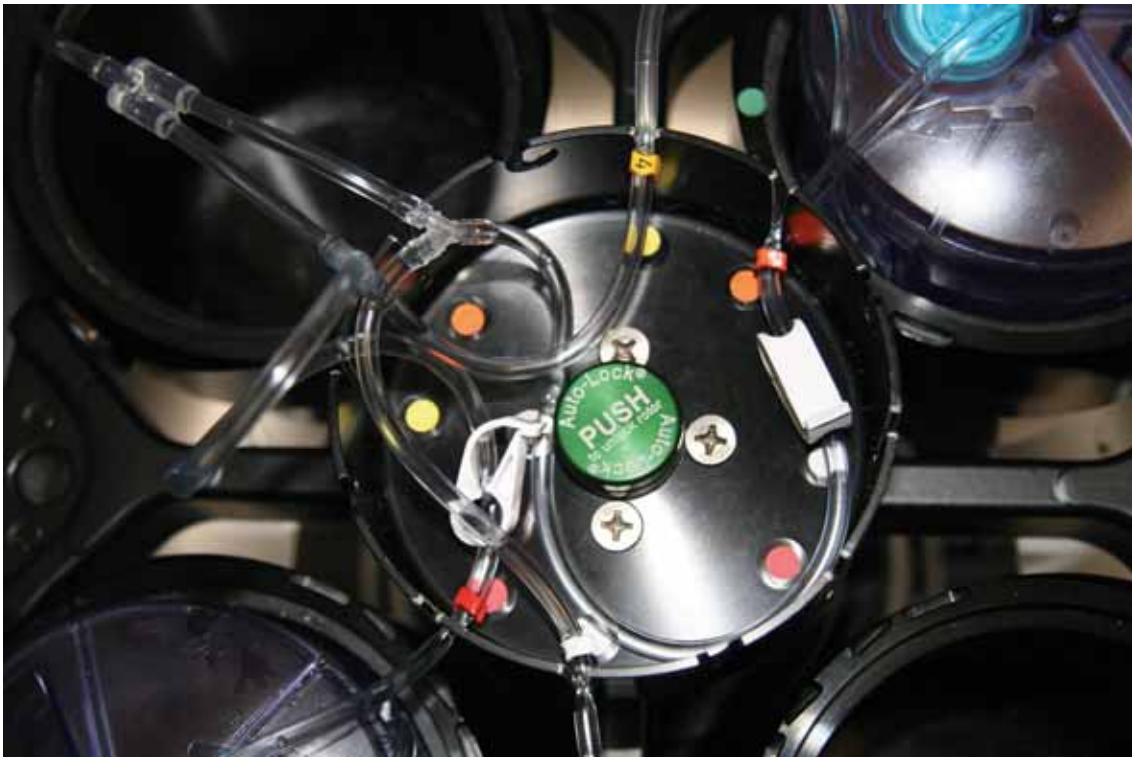
1. Place the Disposables / Control Modules into the centrifuge buckets directly across the rotor from each other.

2. Rotate the Disposables in the centrifuge, pointing the arrows on the top of each Disposable toward the cup that is counterclockwise to the Disposable.



3. Place tubing in the custom rotor hub cup by matching the colors on the tubes to the colors in the cup.

4. Place all additional tubing into the central cup and securely place the cover over the cup.



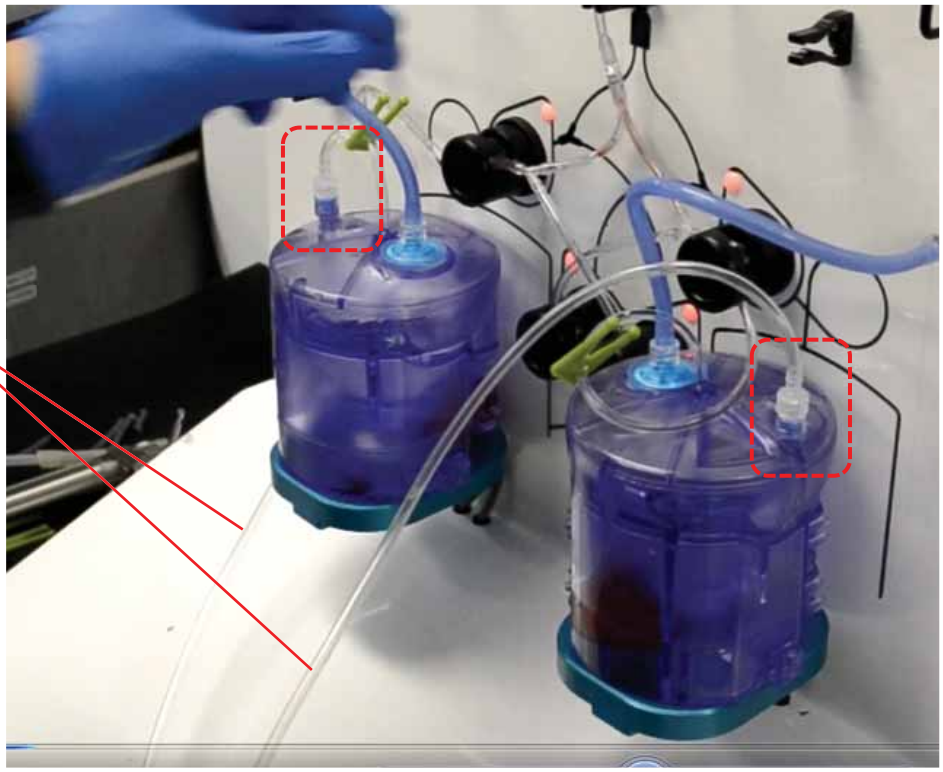
5. Close the centrifuge lid and press **START**.
6. Upon completion of the centrifugation run, remove the cap from the cup.
7. Remove the tubes from the cup and remove the Disposables / Control Modules from the centrifuge.

8. Remove the Disposables from the Control Modules.

9. The data from the Control Modules can be downloaded following the directions in the **Downloading WashPRO™ Control Module** Data section of this manual.

Draining the Waste from the Disposables

1. Place the Disposables back on the rotating holders.
2. Sterile dock the top media bags to the Disposable Set.
3. Replace all tubing connections of the Disposables, as described in the **Mounting the SynGenX™-WASH Disposable Set on the WashPRO™ Workstation** section of this document.
    a. Attach the vacuum / pressure tubes to the filter ports on the tops of the Cartridges.
4. Attach the waste lines coming from the waste buckets to the waste line connector port.



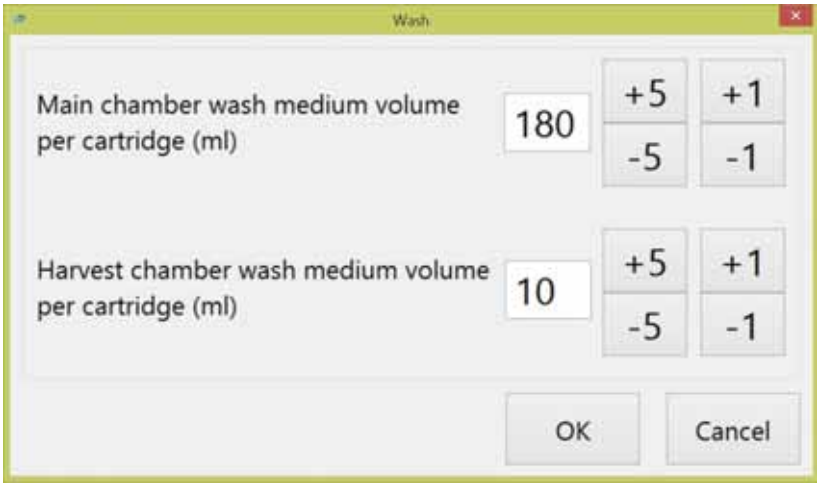
5. Ensure that the waste lines are connected to the waste line connector ports and the waste containers.
6. After the drain process starts, unpinch the sterile weld between the two Y-connectors. Remove the harvest compartment access tubes from slots on the side of the Disposable housings. Unclamp all four clamps.

***NOTE**: All tubing must be unclamped or removed from the slots on the side of the Disposable housings prior to starting the drain process.*

7. On the main screen of the WashPRO Software, press the **DRAIN** button.
8. After draining, the status on the computer will say "Drain Process Complete".
9. Remove the waste line tubing from the Disposables. Discard waste line and waste container per established procedures for handling biohazardous materials.
10. Replace the caps on the waste line connector ports.

Preparing for the Wash Cycle

1. Press the **WASH** button from the main screen of the WashPRO Software.



   a. Input the desired **MAIN COMPARTMENT WASH MEDIUM VOLUME PER CARTRIDGE**

      The main compartment wash medium volume should be between 0 mL and 240 mL. This volume is transferred to the central funnel compartment.

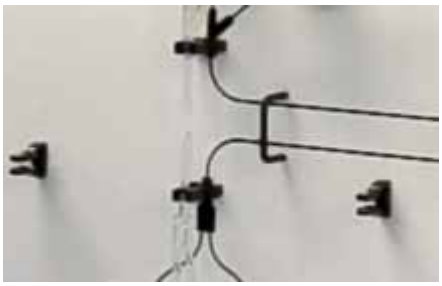
   b. Input the desired **HARVEST COMPARTMENT WASH MEDIUM VOLUME PER CARTRIDGE**.

      The harvest compartment wash volume is the fresh media the harvested cells will be resuspended in. Typical volumes range between 0 mL and 25 mL.

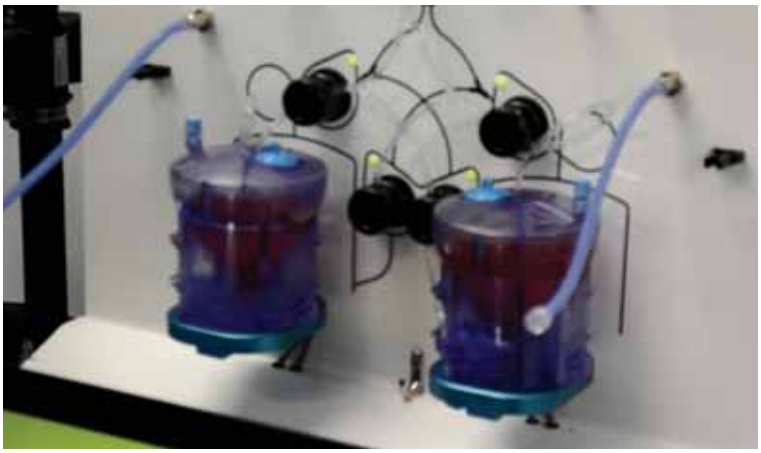
2. Press **OK**.
3. The wash process will begin and the wash window will close.
4. Upon completion of the wash process, put harvest compartment access tubes into the slots on the side of the Disposable housings.
5. Close clamps on the central funnel tubing at the top of each Disposable.

6. Using the tube sealer, seal the tubing between the two Y-Connectors.

7. Using scissors, carefully cut the sealed tubing.



8. Disconnect the vacuum / pressure tubes from the two Disposables.



9. Press the **RESET** button on the WashPRO Software to open the valves.
10. Carefully remove the tubing below the tube-seal from the WashPRO Workstation valves.

11. Remove the Disposables from the rotating holders by pressing on the side release buttons on either side of the Disposable housings.

12. Attach each Disposable to a Control Module.
13. Power on the Control Module, and place the Disposable / Control Module sets in the centrifuge.

The Next Steps

1. The Disposable / Control Module sets are placed in the centrifuge and processed per **The First Centrifuge Run** section of this manual.
2. Following the centrifugation step, the spent media is drained according to the **Draining the Waste from the Disposables** section of this manual**.**
3. Additional wash steps may be performed per the **Preparing for the Wash Cycle** section of this manual.

***NOTE**: Changing media types is possible at the start of any wash step.*

Harvesting the Sample

1. Place the Disposables back on the rotating holders.
2. Leave the clamps on the central funnel tube closed.
3. Tube seal the harvest compartment access tubes and detach.

4. Sterile dock the harvest bag tubes coming from the "Y" to each of the harvest compartment access tubes.

5. Properly place the two welded tubes in the two bottom pinch valves of the WashPRO Workstation.
6. Attach the vacuum / pressure tubes to the air filter on the tops of the Disposables.
7. Attach the waste lines to the waste line connector ports.
8. On the main screen of the WashPRO Software, press the **DRAIN** button.
9. After draining, the status on the computer will read "Drain Process Complete".
10. Remove the waste line drain tubing. Discard the waste line drain tubing per established procedures for handling biohazardous materials.
11. Replace the caps on the waste line connector ports.

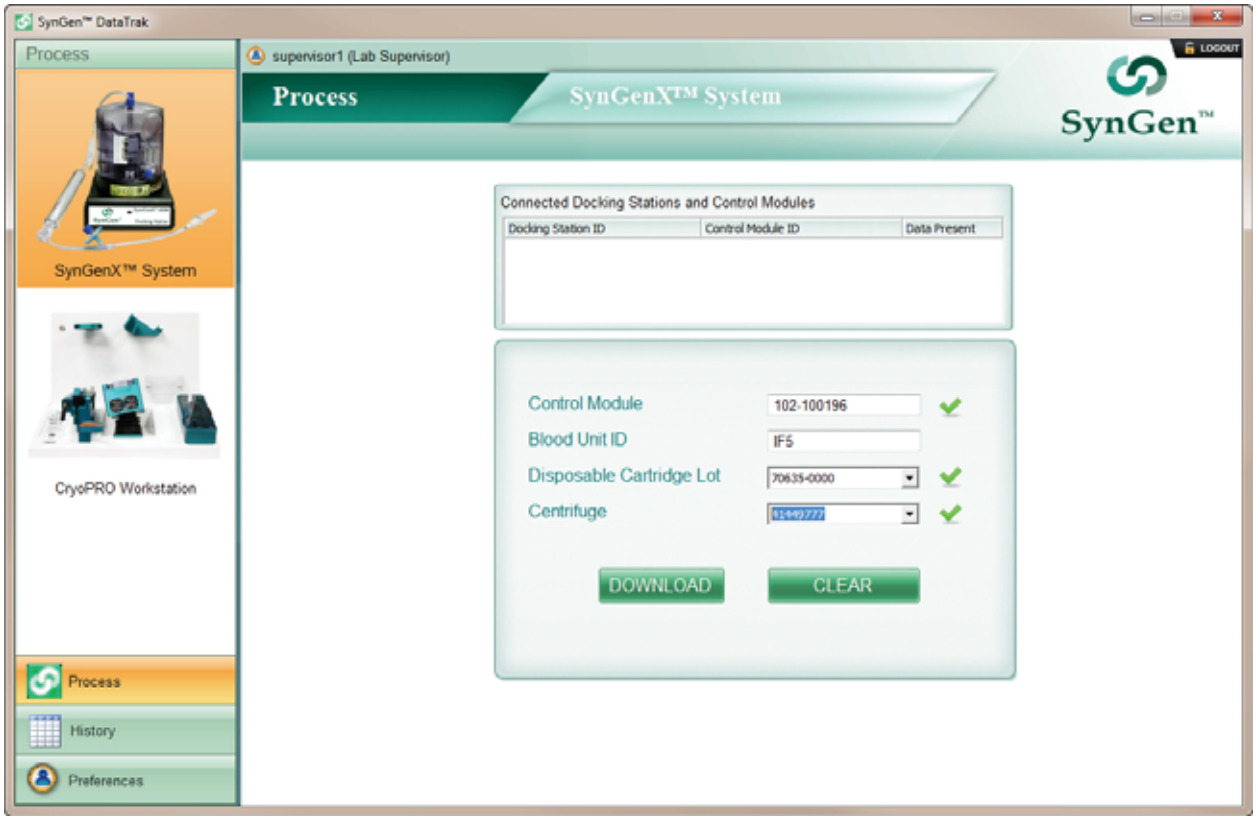
12. Open the weld on the harvest compartment access tubes and remove the cap on the filter of the harvest bag.

13. On the main screen of the WashPRO Software, press the **HARVEST** button.
14. After the Harvest process is complete, tube seal the harvest compartment access tubes, and detach the harvest bag. Discard Disposables per established procedures for handling biohazardous materials.

Download Control Module Data

1. Verify that the Docking Station is connected to the computer via the USB cable.
2. Double click the **SYNGEN™ DATATRAK** icon.
3. Enter Lab Supervisor or Lab Technician User ID, the associated password, and click the **SUBMIT** button.
4. If the User ID was entered incorrectly, an “Invalid User ID” error will occur. If the password was entered incorrectly, a “Password is incorrect” error will occur. Select "Clear" to clear both entries, ensure user ID and password are correct, then click the **SUBMIT** button.
5. Click the **SYNGENX™ SYSTEM** section of the left navigation pane, if not already highlighted.
6. Scan barcode or enter the Control Module serial number and **UNIT IDENTIFICATION** manually.
7. Enter the appropriate **DISPOSABLE CARTRIDGE BARCODE LOT NUMBER** and **CENTRIFUGE** barcode serial number or select the appropriate Disposable lot number and Centrifuge serial number from the dropdown menu.

8. A green checkmark will indicate an acceptable entry. A red "X" will indicate an unacceptable entry. Verify information associated with a red "X" and re-enter as appropriate.



9. Click the **DOWNLOAD** button to download the data located on the Control Module or the **CLEAR** button to clear the fields.
10. After data transfer, the Control Module is ready for subsequent processing.

Processing Report

1. Review report and obtain supervisor approval as appropriate.
2. To add a note to the report, move cursor to the field beside **USER NOTES**. Enter appropriate information and then click the **SAVE USER NOTES** button.
3. To print the report, click the **PRINT** button. The print preview window is displayed. click **FILE**, then **PRINT**. Select the appropriate printer and click the **PRINT** button.
4. To save the report as a PDF file, click the **SAVE AS PDF** button. Select the file location and edit the file name if applicable.
5. To close the file, click the red **X** in the upper right window.

Section 8: Maintenance, Cleaning and Disinfection

Always follow established procedures for handling and discarding biohazardous materials.

Prior to cleaning, power down the WashPRO™ Control Module and unplug the SynGenX™ Docking Station. For cleaning, use a dry cloth or paper towel to wipe away any cell solution or other fluid that has not yet dried. For disinfection, wet a paper towel with a 10% bleach solution or a 70% isopropyl alcohol solution and wipe down all outside surfaces, taking care not to allow any cleaning solution to enter into the Control Module. Allow the wet surface to sit for 5 minutes before drying.

The Control Module should be returned to SynGen Inc. annually for preventive maintenance. Any electromechanical device disposal must follow local regulations.

If an error code is experienced, first consult the "**Troubleshooting**" section of this manual. If the problem persists, please call SynGen at **(844) 363-0709** (in the USA) or at **(916) 256-2423** (international).

Section 9: Customer Service

All WashPRO™ Systems purchased will be supplied with a copy of the User Manual. In addition, professional and competent technical staff will provide end-user training prior to its use and will always be available for specific questions or clarifications.

For assistance with technical or application issues, please contact your local representative or SynGen Inc. Customer Service.

SynGen Inc.
Sacramento, CA USA

Website: www.syngeninc.com
Email: support@syngeninc.com
Customer Service: (844) 363-0709 (in the USA) or (916) 256-2423 (international).
Fax: 1-916-706-0832

Section 10: Troubleshooting

The Troubleshooting section will describe appropriate steps to take in the event that a processing run did not perform as intended. For additional troubleshooting or technical assistance, contact SynGen Inc. Customer Service at (844) 363-0709 (in the USA) or at (916) 256-2423 (international).

SynGenX™-WASH Disposable Set Visual Inspection

The Disposable Set has been designed to be optically clear and provide excellent viewing of the post-processed, separated liquid fractions in each of the compartments as described below:

- ✓ Central Funnel Compartment – center compartment that will contain the waste fraction.
- ✓ Harvest Compartment – side compartment opposite the lot number label that will contain the Buffy Coat fraction. Cells will be transferred to this compartment, suspended in media.

After processing, determine if there are displayed errors on the Control Module or error messages on the Processing Report from the SynGen™ DataTrak Software. Follow instructions under Action by User for the indicated error or message.

In the event that liquids enter the WashPRO™ Control Module, return the Control Module to SynGen Inc. for service

WashPRO™ Control Module Alerts and Error Codes

The table below identifies displayed alerts and error codes for the WashPRO™ Control Module and appropriate user actions.

Displayed Character	Error Description	Action by User
bL	Battery Low. There is insufficient power for a centrifugation process.	Charge the Control Module.
Blank (no display)	Process error.	Review the DataTrak Processing Report for the error message and appropriate user actions.
CF	Cam failure. The Control Module's self-test has determined that the cam has failed to reset to starting position.	Do not use the Control Module for processing. Contact SynGen Customer Service and return Control Module for service.

Displayed Character	Error Description	Action by User
Cr	Calibration required. The Control Module needs to be calibrated to manufacturer's specifications before it can be used for the centrifugation process.	Do not use the Control Module for processing. Contact SynGen Customer Service and return Control Module for service.
dP	Data Present. The data was not downloaded from the Control Module before powering down.	Download the data from the Control Module.
F	Fail. The stratification, depletion, or harvest cycles have failed to complete.	Review the DataTrak Processing Report for the error message and appropriate user actions.

SynGenX™ DataTrak Software Download Error Message

The table below identifies the errors displayed on the Processing Report and appropriate user actions.

Error Message	Description	Action by User
Accelerometer Timeout	The accelerometer failed to update the processor at the start of the centrifugation process so no cells were depleted or harvested.	Place the same loaded Disposable on a new Control Module and repeat the run. Contact SynGen Customer Service and return Control Module for service.
Centrifuge Abort	The Control Module did not detect all the programmed centrifuge cycles.	Verify the centrifuge program used is correct for using the WashPRO System. Re-process the Disposable Set using the correct centrifuge program.
Harvest valve close failed	The harvest pinch valve failed to close when directed. Spent media will be collected along with the desired cells.	The harvested contents of the Disposable can be transferred to a new Disposable Set if additional wash steps are required to achieve the desired reduction of contaminants. Contact SynGen Customer Service and return Control Module for service.

Error Message	Description	Action by User
Harvest valve open failed	The harvest pinch valve failed to open when directed and the harvest did not take place.	Place the same loaded Disposable on a new Control Module and repeat the run. Contact SynGen Customer Service and return Control Module for service.
Harvest Timeout	The harvest pinch valve failed to close when directed.	The pinch valve will automatically close when the Disposable is removed from the Control Module. Contact SynGen Customer Service and return Control Module for service.
Out of FRAM	Control Module ran out of memory to record processing data.	Verify centrifuge cycle times are set properly. Contact SynGen Customer Service for further troubleshooting.
Valve battery threshold error	Battery did not have sufficient charge to rotate cam.	Place the same loaded Disposable on a new Control Module and repeat the run. Charge the Control Module.

SynGenX™ DataTrak Software Launch Error

DataTrak is launched within a framework called Microsoft SQL Server. Occasionally, this server may stop. This can be caused by a range of reasons within the Windows operating system. When the SQL Server stops, a range of error messages may display when the DataTrak software is launched.

Additionally, other errors within the Windows environment may lead to a failure message when DataTrak is launched.

To fix the problem, close all open programs and reboot the computer. DataTrak will launch normally after reboot.

WashPRO™ Software Error Message

In the event an error message is displayed, please contact SynGen Customer Support at (844) 363-0709 (in the USA) or (916) 256-2423 (international) for assistance.

Section 11: Specifications

SynGenX™-WASH Disposable Set Specifications

FEATURE	SPECIFICATION
Capacity (per Cartridge)	40 - 240 mL
Height	5.0 inches (12.7 cm)
Diameter (per Cartridge)	3.9 inches (9.91 cm)
Weight (empty)	0.53 lbs. (0.24 kg)
Sterilization method by manufacturer	Gamma Irradiation*
OPERATING ENVIRONMENT	
Operating Temperature	10 C ≤ Operating Temperature ≤ 35 C
Operating Pressure	70 kPA ≤ Operating Pressure ≤ 106 kPA (526.3 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Relative Humidity	10 % ≤ Operating/Storage Humidity ≤ 95%
STORAGE AND TRANSPORT ENVIRONMENT	
Storage Temperature	7 C ≤ Storage and Transport Temperature ≤ 50 C
Storage Pressure	50 kPA ≤ Storage and Transport Pressure ≤ 106 kPA (376 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Storage Humidity	10 % ≤ Operating/Storage and Transport Humidity ≤ 95%

**The SynGenX-WASH Disposable Set has been subjected to gamma irradiation but validation to confirm sterility has not been completed at this time. These Disposable Sets are not for human use.*

WashPRO™ Control Module Specifications

Feature	Specification
Height	2.3 inches (5.8 cm)
Diameter	3.92 inches (9.96 cm)
Weight	0.66 lbs. (0.3 kg)
Battery Voltage	3.7 volt nominal
Battery Pack	Lithium ion, rechargeable
Control Module Power Input	
DC Voltage	5V
Current	900 mA
Operating Environment	
Operating Temperature	10 C ≤ Operating Temperature ≤ 35 C
Operating Pressure	70 kPA ≤ Operating Pressure ≤ 106 kPA (526.3 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Relative Humidity	10 % ≤ Operating/Storage Humidity ≤ 95%
Centrifugation Speed	Nominal 50-2,000 RCF
Storage and Transport Environment	
Storage Temperature	-20 C ≤ Storage and Transport Temperature ≤ 70 C
Storage Pressure	50 kPA ≤ Storage and Transport Pressure ≤ 106 kPA (376 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Storage Humidity	10 % ≤ Operating/Storage and Transport Humidity ≤ 95%

SynGen™ Docking Station Specifications

Feature	Specification
Height	1.9 inches (4.93 cm)
Width	5.3 inches (13.5 cm)
Depth	5.2 inches (13.2 cm)
Weight	2.2 lbs. (1.01 kg)
Docking Station Power Input	
DC Input Voltage	5V
DC Input Current	4.0A (≤ 4 Docking Stations connected in series)
Docking Station Power Supply	
Power Supply	PMP31-10-B7
DC Output Voltage	5V
DC Output Current	5A
AC Input Voltage	100-240 VAC
Frequency	50 / 60 Hz
Power Consumption	1.0-0.6A
Operating Environment	
Operating Temperature	10 C ≤ Operating Temperature ≤ 35 C
Operating Pressure	70 kPA ≤ Operating Pressure ≤ 106 kPA (526.3 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Relative Humidity	10 % ≤ Operating / Storage Humidity ≤ 95%
Storage and Transport Environment	
Storage Temperature	-20 C ≤ Storage and Transport Temperature ≤ 70 C
Storage Pressure	50 kPA ≤ Storage and Transport Pressure ≤ 106 kPA (376 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Storage Humidity	10 % ≤ Operating / Storage and Transport Humidity ≤ 95%

WashPRO™ Workstation Specifications

FEATURE	SPECIFICATION
Height	42 inches (106.68 cm)
Width	33 inches (83.82 cm)
Depth	14 inches (35.56 cm)
Weight	57 lbs. (25.85 kg) – without the tube sealer
WASHPRO WORKSTATION POWER SUPPLY	
AC Line Voltage	100-240 VAC
Frequency	50 / 60 Hz
Power Consumption	1000 Watts Max
OPERATING ENVIRONMENT	
Operating Temperature	10 C ≤ Operating Temperature ≤ 35 C
Operating Pressure	70 kPA ≤ Operating Pressure ≤ 106 kPA (526.3 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Relative Humidity	10 % ≤ Operating / Storage Humidity ≤ 95%
STORAGE AND TRANSPORT ENVIRONMENT	
Storage Temperature	-20 C ≤ Storage and Transport Temperature ≤ 70 C
Storage Pressure	50 kPA ≤ Storage and Transport Pressure ≤ 106 kPA (376 mmHG ≤ Operating Pressure ≤ 797 mmHG)
Storage Humidity	10 % ≤ Operating / Storage and Transport Humidity ≤ 95%

Section 12: Warranty

SynGen Inc. warrants to original purchaser that the WashPRO™ Control Module and SynGen™ Docking Station will be free from defects in material or workmanship for one (1) year from date of shipment.

SynGen also warrants that replacement parts will be free from defects in material workmanship for a period of ninety days (90), or maximum time required by applicable local law, from date of shipment of replacement part.

SynGen products are designed and manufactured to provide trouble free and reliable performance when properly maintained and used in accordance with the instructions provided in this manual. Each Control Module and Docking Station (referred to as "Device") is carefully inspected and tested before shipping.

In case of device failure or malfunction, SynGen will replace or repair the concerned device according to the agreement in place.

Device failure or malfunction for reasons other than those caused by defects in materials or manufacturing defect (such as improper handling of the machine, misuse, accident, or non-compliance with the User Manual) is not covered under the SynGen warranty program and such device will be replaced or repaired at the charge of the end-user.

Any alterations or modification made to the device (other than those made by SynGen) will render the warranty null and void. SynGen will not be responsible for any consequential or incidental damages resulting from device malfunction or loss of use of device.

SynGen shall under no circumstances be liable for consequential or economic damage that may be an indirect or direct consequence of a defective part.